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COMMITTEE PRINT

FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY

AN INFORMATION PAPER

PREPARED BY THE STAFF OF THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

SEPTEMBER 1982

This document has been printed for information purposes. It does not offer findings or recommendations by this committee

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LETTER OF TRANSMITTAL

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, D.C., September 2, 1982.

Hon. JOHN HEINZ,
Chairman, Senate Special Committee on Aging.

DEAR MR. CHAIRMAN: As you know, for the past year, the staff of the Special Committee on Aging has been involved in an intensive review of problems related to the purchase and use of pacemakers in the medicare program. The report enclosed details the staff's activities and the problems identified.

Many people were helpful in the progress of this review, but five of these deserve our special thanks: Dr. Seymour Furman, Montefiore Hospital and Medical Center, New York City; Dr. Victor Parsonnet, Beth Israel Hospital, Newark, N.J.; Dr. Jerry Griffin, Baylor University, Houston, Tex.; Dr. Robert G. Hauser, Rush-Presbyterian St. Luke's Medical Center, Chicago, Ill.; and Dr. Michael Bilitch, University of Southern California School of Medicine, Los Angeles, Calif. These individuals and their colleagues in the leadership of the North American Society of Pacing and Electrophysiology have performed a valuable service by recognizing, and beginning to address on a professional level, many of the problems identified in this report. On a personal level, these five pacemaker experts contributed significantly with their generous availability, graciousness, and patience.

I would also like to acknowledge the dedicated work of Bill Halamandaris and David Holton in preparing this report and in the inquiry it reflects.

Sincerely,

JOHN ROTHER, *Staff Director.*

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FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY

Chapter 1

O' ERVIEW

The inquiry that led to this report was initiated by a constituent complaint and public reports of excesses in the sale of cardiac pacemakers. The constituent, an angry 88-year-old medicare beneficiary, complained that an explicit pacemaker replacement warranty had been dishonored to the effect that medicare was required to pay for services more properly the responsibility of the manufacturer. Public reports sketched a series of abuses related to the profitability of the industry, its competitiveness, and the reflection of these two facts in the industry's sales practices.

Medicare pays for 80 to 90 percent of all pacemaker procedures in this country. Estimates are that costs associated with the hospitalization, surgical fees, pacemaker cost, and related medical procedures associated with pacemaker implantation, followup, and monitoring, total $10,000 to $18,000 per patient. About 150,000 people in the United States will receive pacemakers this year. When the costs associated with these anticipated implants are added to the costs of following and monitoring the 500,000 existing pacemaker patients in this country, total medicare costs will exceed $2 billion in 1982.

The necessity or appropriateness of as much as half that total cost can be questioned. The elements forcing this conclusion include the following:

Unreasonable cost.—Pacemakers costing $600 to $900 to manufacture are being billed to hospitals (the direct purchaser) for $2,000 to $5,000. Hospitals, without any correlating expense, increase the cost by 50 to 150 percent and pass the total on to medicare and other third-party payers.

Overutilization.—There is increasing evidence that pacemakers are prescribed unnecessarily and overutilized. Estimates from physicians associated with medical centers across the country estimate 30 to 50 percent of all pacemaker implants are unnecessary. The most egregious example found involved two physicians who implant two pacemakers in each patient. The second pacemaker is justified as a precaution in the event the first fails. Allegations of overutilization are supported by national comparisons. The United States has a rate of pacemaker utilization more than twice that of any other nation in the free world.

Warranties.—Around 30 percent of all pacemaker operations in any given year involve replacement of the device. Most manufacturers offer replacement credit, figured into the cost of the device,

that includes device replacement and the payment of "uninsured medical expenses."

The payment of "uninsured medical expenses" limits the manufacturer's exposure to that operative expense not paid by medicare or other third-party payers, regardless of fault, performance, or recall. In effect, the manufacturers have inappropriately succeeded in subordinating their responsibility for product liability to medicare. To the extent that replacement credits are offered for the devices, there is no method of tracing compliance and assuring payment to medicare.

Monitoring.—By every measure, frequency schedules and payment rates adopted by medicare for followup and monitoring of pacemaker performance are generous. Since the manufacturers provide the essential equipment "free of cost," frequently set up the system, train the personnel, and provide medicare billing guidance; the only expense to the physician or clinic is the incremental use of staff. In the words of one salesman, "It's a lucrative business, followup on pacemakers. Medicare reimburses anywhere from 80 percent of $28 to $60, depending on a number of factors I can't figure out. The lowest reimbursement I've ever seen was 80 percent of $28. It takes the secretary over the telephone about 3 minutes." Another salesman offered the following projection, "You can make a quarter of a million dollars doing this * * * I know a group here in New York, they have 400 pacemaker patients, 400, and they make a quarter of a million dollars."

Kickbacks, consulting fees, rebates, and other improper inducements to do business.—Because of the excessive profitability of the industry, the essential comparability of products, and the intense competition found in the industry, a number of "creative marketing devices" have evolved. These include:

—Stock or stock options offered as a reward for "consulting" arrangements.
—Payments of $200 to $25,000 for "clinical evaluations" of new products.
—Direct cash rewards, in one case $150, for each of the manufacturer's pacemakers implanted.
—Liberal payments of "unreimbursed medical expenses" which, in practice, often amount to incentives to physicians to "write your own rebate."
—Vacations in the Caribbean.
—Fishing excursions to Alaska and the Gulf of Mexico.
—Ski trips to Colorado.
—Las Vegas gambling junkets.
—Expensive gifts, including gold-plated shotguns and gold watches.
—The "gift" of pacemaker accessories, including devices ranging in cost from several hundred to several thousand dollars, as an inducement to do business.

In the process of this investigation, we found most of the abuses present in the pacemaker industry to be notorious and of long standing. The General Accounting Office, Securities and Exchange Commission, Federal Bureau of Investigation, Federal Trade Commission, Veterans Administration, and committees of both Houses of Congress have initiated related inquiries into the performance,

marketing, and competitiveness of pacemakers; questions of warranty, and/or persistent allegations of kickbacks, bribery, stock manipulation, and related criminality.

Despite these activities the problems persist. It appears the reason for this fundamental failure is related to the fragmentation of Federal responsibility, the failure to communicate findings even when the need for communication is recognized, and the absence of leadership in attacking these problems from the Department of Health and Human Services. Significantly, until this year, the one Government agency least active in identifying and attempting to remedy the problems within the pacemaker industry is the agency with primary responsibility, the Department of Health and Human Services.

The key to the abuses found in the pacemaker industry lies in the symbiotic relationship of the physician and the pacemaker salesman. Although these two individuals are responsible for the purchase decision, neither has any incentive to be cost-conscious.

In the words of one salesman:

> Prices aren't that different. What it comes down to is service. We do anything you can think of. And, if you think of it, and we aren't doing it, we'll start.

Among the services the pacemaker salesman performs are:

—Attending and assisting in about three-quarters of the pacemaker operations performed in this country.

—Training, or arranging for training of inexperienced physicians interested in initiating a pacemaker practice.

—Setting up and training personnel to operate pacemaker follow-up clinics

—Providing medicare guidelines, billing codes, and frequencies, as well as specific advice on how best to manipulate the medicare program.

There are about 400 pacemaker salesmen in this country. Minimum salaries for most are about $50,000. Many salesmen earn several hundred thousand dollars a year. At least a dozen earn more than $1 million a year. In the words of one salesman, "the industry is totally unconcerned with price. Medicare reimburses and they just don't care. God bless them, I love it."

Chapter 2

INTRODUCTION

On April 19, 1981, the Philadelphia Inquirer carried a detailed report (appendix A) of problems in the pacemaker industry. The Inquirer focused on the role of pacemaker salesmen, their relationship to the physicians implanting cardiac pacemakers, and the impact this relationship has on the utilization of the devices designed to stimulate regular contractions in a heart whose natural electrical system is impaired.

The Inquirer painted a picture of an intensely competitive industry. Highly motivated salesmen—some earning $1 million a year—were said to be in competition for lucrative physician accounts through a number of innovative marketing techniques. The inducements cited ranged from company stock options, lavish parties, paid vacations, and all kinds of "technical assistance," to the frequent presence of the salesman in the operating room assisting while the pacemaker was being implanted and tested.

Four months later, in September 1981, the committee received a related letter from a Florida constituent, Madeline Garman. Mrs. Garman's letter (appendix B) addressed to Senator Lawton Chiles, ranking minority member of the committee, complained that a pacemaker supplied her in 1979, and guaranteed for 10 years, had failed after only 2 years. Despite a warranty from the manufacturer stating the pacemaker would be replaced at no cost in the event of failure, 90 percent of the replacement cost was borne by medicare.

Mrs. Garman asked:

> How many hundreds of these were called in over the country and how many thousands of dollars (were) spent by medicare? It's one of the ways medicare is being milked and I'm incensed over it.

The conjunction of these two events initiated the inquiry that led to this report. In the intervening period, staff has completed an extensive review of public material—trade journals, newsletters, technical articles, and newspaper files; examined the files of four government agencies with past or present related inquiries; interviewed experts in the field (practicing cardiologists and surgeons), beneficiaries, responsible government officials, and law enforcement agents; with the assistance of the General Accounting Office reviewed a sample of 2,500 invoices for pacemakers implanted in a 27-month period; attended practitioners' professional meetings, regulatory reviews, and pacemaker implants. At the conclusion of these activities, when it was apparent that the key to the abuses was the physician-salesman relationship, the committee staff arranged to "test buy" devices in two States, California and New

York. In this context, the committee learned firsthand of the many inducements offered to do business.

The modern pacemaker is a marvelous device, capable of sustaining life in many instances and significantly improving the quality of life in many more. It is the treatment of choice for a number of cardiac conditions. West German Chancellor Helmut Schmidt has one. As do Soviet President Leonid Breshnev, Congresswoman Millicent Fenwick, painter Joan Miro, and half a million others ranging in age from less than a year to Arthur Reed, our Nation's most senior citizen, at 122. Over 150,000 people will receive pacemakers in this country in 1982.

The average age of a pacemaker recipient is 71. Medicare pays for 80 to 90 percent of all pacemakers implanted in the United States. Apparently, these payments are made without questioning cost or appropriateness of device. Medicare also pays for followup care, including physician's visits and transtelephonic monitoring.

At the current rate of $10,000 to $18,000 for the evaluation, prescription implantation, followup, and monitoring of pacemaker patients, total cost associated with this therapy exceeds $2¼ billion. We estimate medicare's share of this total will exceed $2 billion in 1982.

Because of the lack of payment screens and the perverse incentives of medicare's "retroactive reasonable cost" payment mechanism, the most apparent competition present in the industry is to see who can produce the most expensive pacemaker. This price insensitivity has led to enormous waste and encouraged other abuses, including "creative marketing." In the words of one salesman interviewed in California, the marketing of pacemakers is "a filthy business."

Rebates, kickbacks, and other inducements to do business are frequently offered. Warranties are often misrepresented and dishonored to the effect that medicare is asked to absorb the additional costs. The use of pacemakers appears excessive, as do their cost to the program and profitability to the manufacturer, salesman, physician, and hospital.

It appears as much as half of the total $2 billion expended by medicare for pacemakers may be inappropriately expended.

Chapter 3

BACKGROUND

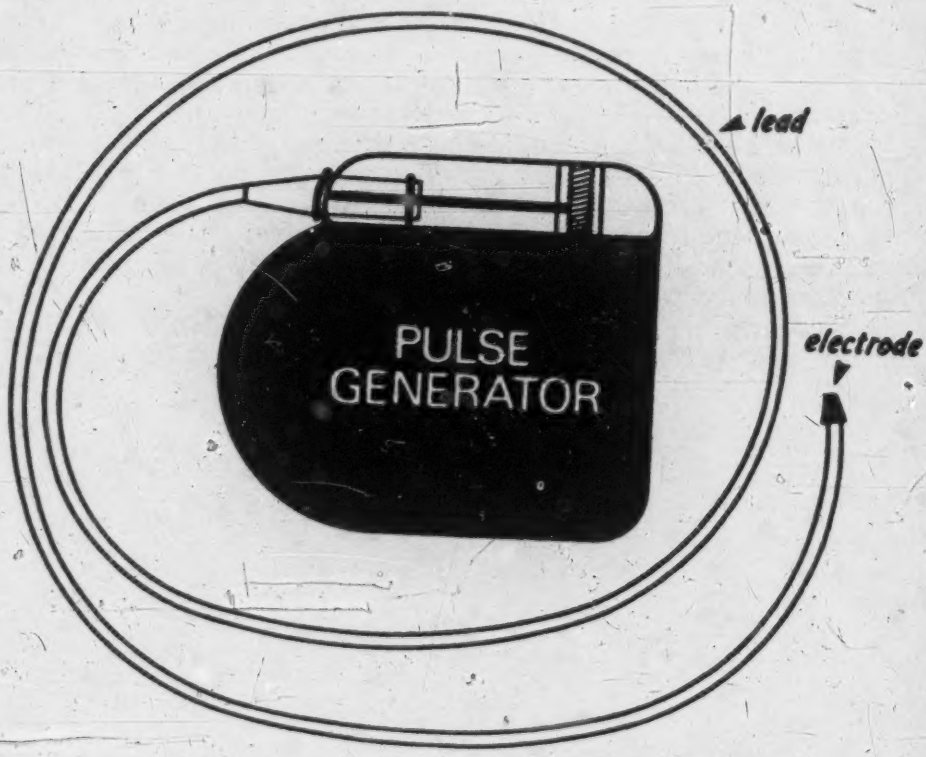
A. Definition

The human heart has a natural pacemaker called the sinoatrial node. The sinoatrial node is a small cluster of specialized cells located at the top of the heart which send electrical impulses through the heart at regular intervals.

When this natural device becomes defective, through heart damage that blocks the path of the impulses (heart block) or other causes, a manmade device called a cardiac pacemaker is used to stimulate the heart into rhythmic beating.

Generally, an artificial pacemaker has two parts—the pulse generator and the lead-electrode (figure 1). The pulse generator includes electrical circuitry and a power source to develop the electrical impulse. The lead-electrode delivers the impulse to the heart.

Figure 1



B. Pacemaker Development

The first artificial pacemaker was developed in 1932 by Albert Hyman, a physician at Beth David Hospital, New York City. It was an external device designed for the "resuscitation of the stopped heart."[1] It was a large generator, driven by a spring motor. It weighed about 7 kilograms.

It took 26 years and the key development of the transistor before the first implantable pacemaker was developed in 1958. These first implantable pacemakers weighed about 200 grams (7 ounces) and fired electrical impulses at a fixed rate, even if those impulses competed with the natural rhythm of the heart.

By 1970, 15 years after the development of the first implantable device, the weight had dropped to 160 grams (5.6 ounces). The industry had developed "demand" pacemakers which stimulate the heart only when its natural rhythm falls below an established level.

Modern pacemakers are the size of a silver dollar and weigh less than 56 grams (2 ounces). They can be "programed" to modify operating characteristics (such as pulse rate) without surgery. Dual chamber pacemakers have been developed to duplicate the natural rhythm of the heart by pacing both chambers of the heart. Software pacemakers, including extensive telemetry, are anticipated within the next year.

Initially, the primary source of power for the pulse generator of a pacemaker was a mercury-zinc battery. This power source kept the pacemaker operating for about 2 years before the unit had to be replaced. Currently, most pacemakers are powered by lithium batteries. Since the lithium-iodine chemicals employed are less dense than mercury and zinc, more energy can be fitted into the same sized battery. Longevity projections for lithium batteries estimate a useful life of 7 to 10 years in most cases.

Table 1 presents the principal milestones in the development of the cardiac pacemaker.

Table 1.—*Milestones*

1959	Dr. William Chardack (New York) performs the first pacemaker implantation.
1960	The first implantable pacemaker commercially available in the United States was manufactured by Medtronic. This pioneer pacemaker was a fixed rate unit powered by a series of mercury-zinc batteries. These epoxy encapsulated units had a service life of approximately 2 years.
1963	Cordis emerges as the first major competitior to Medtronic.
1965	American Optical receives the patent for "demand" pacemakers.
1972	Cordis introduces the first programable pulse generator with noninvasive rate and output programability.
1973	Cardiac Pacemakers, Inc., introduces the first lithium powered hermetically sealed implantable pulse generator, which pioneered a new, long-lived generation of power sources.
	Intermedics is formed.
	Pacesetter Systems introduces a rechargeable pacemaker.
1976	Cardiac Pacemaker, Inc., and Intermedics introduce the first long-lived lithium-powered pacemaker extending service life to 6 or more years.

[1] PACE, vol. I, July–September 1978, page 371.

TABLE 1.—*Milestones*—Continued

1977	Intermedics introduces the first thin line of lithium-powered pulse generators.
	Intermedics and Pacesetter introduce multiprogramable pulse generators.
1981	Intermedics introduces the first multiprogramable dual chamber pacemaker.

C. PACEMAKER IMPLANTATION PROCEDURE

The implantation of early pacemakers required the opening of the chest, exposing the heart, and manually implanting the electrodes onto the heart. The procedure was complicated, risky, and required extensive hospitalization.

Today, most pacemaker leads are connected intravenously. The chest need not be opened. The average operation, absent complications, is about 45 minutes. In most cases, the hospital stay should not exceed a few days.

The procedure consists of an incision below the collarbone on the chest. The surgeon performing the operation cuts down to the subclavian vein. Then the surgeon, or a cardiologist, runs the lead through the vein into the heart. The surgeon connects the pulse generator to the lead, makes a pocket under the skin, and closes.

D. THE PACEMAKER INDUSTRY

According to the Food and Drug Administration, about 25 companies manufacture pacemakers in the free world. Sixteen of these (table 2) are registered with the FDA to manufacture pacemakers in the United States. Five of the sixteen companies listed (Medtronic, Intermedics, Pacesetter, Cordis, and Cardiac Pacemakers, Inc.) control well over 90 percent of the domestic market.

TABLE 2.—*Pacemaker Manufacturers*

American Pacemaker Corp., 10 Sonar Drive, Woburn, Mass. 01801.
Cardiac Pacemakers, Inc., 4100 North Hamline Avenue, St. Paul, Minn. 55112.
Cordis Corp., 10555 West Flagler Street, Miami, Fla. 33172.
Daig Medcor, Inc., 14901 Industrial Road, Minnetonka, Minn. 55343.
Ela Medical, 98–100 Rue Maurice Arnoux, Montrouge 92120, France.
Medtronic, Inc. (Rice Creek facility), 6970 Old Central Avenue, Minneapolis, Minn. 55432.
Siemens Elema AB, S–17195, Solna, Sweden.
Telectronics Proprietary, Ltd., 8515 East Orchard Road, Englewood, Colo. 80111.
Biotronik Sales, Inc., 6024 SW. Jean Road, Suite H, Lake Oswego, Oreg. 97034.
Coratonic, Inc., 300 Indian Springs Road, Indiana, Pa. 15701.
Cordis Europa, N.V., 8 Costeinde, Roden, Netherlands.
Edwards Pacemaker Systems, 1923 SE. Main Street, Irvine, Calif. 92714.
Intermedics, Inc., 240 Tarfon Inn Village, Freeport, Tex. 77541.
Pacesetter Systems, Inc., 12740 San Fernando Road, Sylmar, Calif. 91342.
Telectronics, Ltd., 301 West Vogel Avenue, Milwaukee, Wis. 53207.
Vitatron Medical, Inc., 1 Gateway Center, Newton, Mass. 02158.

The industry is immensely profitable, intensely competitive, volatile, and litigious (the committee identified several hundred suits—generally related to sales practices—involving pacemaker firms in the last 10 years). Since medicare and other third-party payers pay for all the pacemakers implanted, price is considered irrelevant.

Competition manifests itself in aggressive marketing and product innovation.

Medtronic is the leading manufacturer of pacemakers in the United States and the world. Manufacturers of the first commercial pacemaker in 1960, Medtronic currently controls about 40 percent of the U.S. market. In 1960, it was a small firm operating out of a garage. It had sales of about $3 million. Medtronic is currently a conglomerate, earning over $335 million in fiscal year 1982. It's estimated Medtronic will sell about 100,000 pacemakers worldwide in 1982.

Intermedics, currently the second largest domestic manufacturer of pacemakers, did not make its first pacemaker until 1974. It is cited as a classical example of entreprenuerial management. Started by former Medtronic employees, Intermedics relies heavily on a highly motivated sales force.

Organized as independent sales organizations, these salesmen operate essentially small business franchises selling Intermedics products in a given territory for a percentage of the sales price. Fueled by aggressive marketing, the company's sales grew from $2.2 million in 1975 to $155 million in 1981.

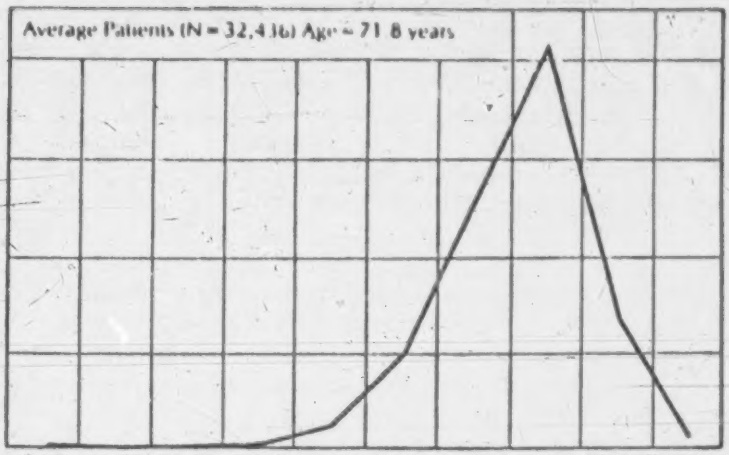
Pacesetter Systems has also demonstrated aggressive sales techniques. Following Intermedics lead and adopting the same sales incentives, the company has increased sales from $5 million in 1978 to about $60 million in 1982. Pacesetter appears to be the fastest growing pacemaker firm. Its present market share of 13 percent at current rates will increase to 16 percent by 1984.

Both Cordis and Cardiac Pacemakers, Inc., achieved initial success by innovative technical achievements. Cordis was the first firm to market programable pacemakers. CPI, now a subsidiary of Eli Lilly & Co., initiated the use of lithium-iodine power cells. Since that time, however, neither firm has shown the marketing aggressiveness necessary to compete in the current industry. Cordis' market share has fallen to about 12 percent. CPI share is about 8 percent.

E. Pacemaker Utilization

About 18 percent of the $287 billion spent by Americans for health care in 1981 was connected, in one way or another, with heart ailments. The American Heart Association reports that about 40 million Americans have some form of heart disease that requires treatment. About 500,000 of these are pacemaker patients.

Most pacemaker patients are seniors. Implants in patients aged 60 to 80 account for two-thirds of all implants. In these patients, the conditions necessitating a pacemaker are said to relate to a natural deterioration of the heart. For the minority of younger patients, pacemaker use is generally related to a heart defect or injury. The following chart illustrates pacemaker usage by patients' age.



Since 1973, annual pacemaker sales have increased from $50 million to more than one-half billion dollars in 1982. Sales are projected to double to $1 billion by 1985. If related medical procedures—diagnosis, surgical fees, hospital expenses, followup, and monitoring—are added, expenditures for pacemaker patients will exceed $2¼ billion in 1982.

The growth in the use of pacemakers reflects its growing acceptance in the medical community. Initially, pacing was used primarily for treatment of complete heart block. Later, pacing expanded to conditions of partial heart block, and more recently, sick sinus syndrome.

According to Dr. Michael Bilitch, Pacemaker Center, University of Southern California, if all of the 500,000 pacemakers carried by Americans stopped tomorrow, about 10 percent would experience significant complications. In about 1 to 5 percent, death would result. Another 10 percent would not know the difference. The rest would notice a difference in their quality of life.

A significant portion of all pacemaker operations are replacements. In all, replacements accounted for as much as 40 percent of the total number of pacemakers sold in 1975. About 160,000 of 220,000 implanted mercury-zinc units were replaced. With the advent of lithium power that percentage has decreased, but replacements still remain significant.

Industry sources project 90 percent of patients who receive pacemakers die within 10 years of their first pacemaker operation. About 20 percent die within the first year from causes not associated with the condition initiating the pacemaker placement. For the rest, the odds are that the pacemaker will have to be replaced within 3½ years.

F. Medicare Payment for Pacemaker Procedures

The medicare program, which is authorized under title XVIII of the Social Security Act, consists of two separate but complementary types of health insurance for the aged and certain disabled persons. Part A, the hospital insurance program, provides protection against hospital and related institutional costs. Part B, the supplementary medical insurance program, covers physicians' services and a number of other medical services.

The part A program pays the "reasonable costs" for up to 90 days of inpatient hospital services during each benefit period, subject to specified deductible and coinsurance amounts. For the first 60 days, the program pays the reasonable cost of all covered services, except for an initial inpatient hospital deductible ($260 in 1982).

Part A generally does not cover physician services rendered to hospital inpatients; payment for such services is made under part B. However, services rendered by interns and residents under an approved teaching program and, under certain circumstances, physician services rendered in a teaching hospital, are included as part of the part A hospital benefits.

The implantation of a pacemaker is paid for by medicare as an operative procedure billed by the hospital. The hospital bill includes the pacemaker, hospitalization, and related procedures (laboratory charges, pharmacy, radiology, etc.). These payments are based on "reasonable costs" defined as the actual cost incurred in delivering health services, excluding any part of such items found to be unnecessary for the efficient delivery of needed services (section 1861(v)(1)(A) of the Social Security Act).

Physician services, including those of the primary physician, cardiologist, and surgeon, are billed under part B. These services are reimbursed at 80 percent of customary charges. Customary charges vary by region and physician. Rates for pacemaker procedures were established at the time medicare was enacted. At that point, pacemaker technology was in its infancy. Related medical procedures were complicated and difficult. Despite significant changes in the complexity of pacemaker technology and the difficulty of operative procedures, reimbursement levels have remained largely unchanged and unquestioned.

Postoperative care and monitoring services are reimbursed under part B of medicare. Medicare guidelines allow three visits to the physician or pacemaker clinic for pacemaker evaluation within the first 12-month period after the patient receives the pacemaker. Thereafter, medicare will pay three evaluations within the next 6 months, and four evaluations in each 6-month period thereafter. If the patient is also receiving transtelephonic monitoring, payment for clinic visits is reduced to three visits during the first 12 months, and four visits for each succeeding 12-month period.

Transtelephonic monitoring is covered under two frequency schedules—one for mercury-zinc powered units (no longer implanted), and a second for lithium battery-powered devices. The frequency schedules are reprinted below. Fees for this service are variable.

1. Mercury-zinc battery powered pacemakers:

(a) Both pacemaker and lead implanted: first month, once per week; second through fifteenth months, once every 4 weeks; sixteenth through eighteenth months, every 2 weeks, nineteenth month through failure, once per week.

(b) Only pacemaker implanted, lead not changed: first week, once per week; third week through fifteenth month, once every 4 weeks; sixteenth through eighteenth month, once every 2 weeks; nineteenth month through to failure, once per week.

2. Lithium battery-powered pacemakers:

(a) Both pacemaker and lead implanted: first month, once per week; second month through failure, once every 4 weeks.

(b) Only pacemaker implanted, lead not changed: first 2 weeks, once per week; third week through to failure, once every 4 weeks.

It should be noted that medicare recognizes the cost of the transmitting device as one component of the total charge for monitoring services. A separate charge for a transmitting device furnished to a patient is considered inappropriate. Medicare's pacemaker monitoring guidelines are included at appendix C.

Chapter 4

REGULATORY ACTIVITIES

A. Overview—The FDA

Primary responsibility for the regulation of medical devices lies with the Food and Drug Administration (FDA). The FDA is an agency within the U.S. Department of Health and Human Services established to protect the public from the potential health hazards presented by adulterated and mislabeled foods, cosmetics, medical devices, and drugs.

Generally, the FDA's responsibilities include the establishment of written and physical standards for biologic products; licensing manufacturers of biological products; evaluation of the claims for new drugs; inspection of manufacturer facilities for compliance with FDA standards; developing guidelines on good manufacturing practices; developing standards for the safety and effectiveness of over-the-counter drugs; monitoring the quality of marketed drugs through product testing; surveillance and compliance programs; conducting research on the safety of food additives; conducting research on the effects of radiation exposure; development of programs and standards dealing with veterinary drugs; conducting research on the biological effects of potentially toxic chemical substances found in the environment; and developing regulations on the safety, efficacy, and labeling of medical devices.

To carry out these activities, the FDA is divided into six bureaus: Drugs, Foods, Biologics, Radiological Health, Veterinary Medicine, and Medical Devices. The Bureau of Medical Devices is responsible for the FDA's policy on the safety efficacy, and labeling of cardiac pacemakers and other medical devices (instruments and equipment intended for use in the diagnosis, treatment, prevention, and cure of disease), and in vitro diagnostic products (substances used to perform diagnostic tests on specimens taken out of a body).

B. Enforcement Activities

To monitor compliance with the law, the FDA employs inspectors and chemists who are authorized to inspect factories and other places where food, drugs, cosmetics, and medical devices are manufactured. FDA inspectors can demand and examine records maintained by manufacturers, shippers, and sellers of goods regulated by the FDA.

The FDA approves the safety and efficacy of new medical devices before they can be marketed, establishes regulations for the labeling of products, and investigates consumer complaints about any of the products it regulates.

In the event of a violation of law, the FDA has the following enforcement options:

Regulatory letter.—The FDA can send an enforcement document to the top management of a firm, stating that legal action will be taken unless the apparent violative product conditions are corrected.

Recall.—After the FDA, or a manufacturer, fines that a product is defective, a recall may be initiated to remove the product from the marketplace. Recalls may be made voluntarily by the manufacturer, or conducted at the request of the FDA. In some cases, recalls may involve the correction rather than the removal of the product. The Administration monitors the progress of recalls to insure that all affected inventory is corrected or removed from sale.

Injunction.—If a voluntary recall is not effective, the FDA may initiate a civil action against the individual or company involved. Such actions usually seek to stop the continued manufacture or distribution of products that are in violation of the law.

Citation.—A firm or an individual may request the opportunity for an informal hearing to show cause why a criminal prosecution for an apparent law violation should not be forwarded by the FDA to a U.S. attorney for prosecution.

Seizure.—The FDA can initiate a seizure by filing a complaint with the U.S. district court where the goods to be seized are located. A U.S. marshal is directed by the court to take possession of the goods until the matter is resolved.

Prosecution.—The FDA may file a criminal action against an individual or a company that is charged with violating the laws administered by the agency.

Table 3 summarizes FDA enforcement actions from 1978 to 1981.

TABLE 3.—FOOD AND DRUG ADMINISTRATION ACTIONS (1978–81)

Type of action	Fiscal year 1978		Fiscal year 1979		Fiscal year 1980		Fiscal year 1981	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Seizures	501	34	681	42	577	32	335	41
Mass seizures	42	3	56	4	45	3	17	2
Direct reference seizures	102	7	122	8	47	3	39	5
Regulatory letters	534	36	462	29	416	23	247	30
Direct reference regulatory letters	71	5	53	3	492	27	26	3
Injunctions	66	4	67	4	58	3	23	3
Citations	57	4	63	4	70	4	31	4
Direct reference citations	12	<1	10	<1	30	2	17	2
Prosecutions	39	3	36	2	32	2	40	5
Direct reference prosecutions	0	0	3	<1	0	0	0	0
Use prohibited letters	11	<1	30	2	20	1	17	2
Civil penalties	0	0	0	0	2	<1	7	1
License suspensions/revocations	11	<1	14	<1	17	1	5	<1
Revocations	23	2	17	1	7	<1	6	<1
Disqualifications	2	<1	1	<1	5	<1	0	0
Decertifications	0	0	0	0	0	0	4	<1
Emergency permits	0	0	0	0	3	<1	4	<1
Detentions	2	<1	2	<1	0	0	1	<1
Grand total	1,473		1,617		1,821		819	

RECALLS

The FDA has published guidelines covering three classes of recalls plus market withdrawals and stock recoveries. These are defined as follows:

Class I recalls.—A class I recall is a situation in which there is a reasonable probability that the use of, or exposure to a violated product, will cause serious adverse health consequences or death.

Class II recalls.—A class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

Class III recalls.—A class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

Market withdrawals.—Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, such as normal stock rotation practices, routine equipment adjustments and repairs, etc.

Stock recovery.—A stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, such as the product which is located on premises owned by or under the control of the firm where no portion of the lot had been released for sale or use.

Table 4 indicates the number of recalls initiated by the FDA from 1977 through 1981.

TABLE 4.—FOOD AND DRUG ADMINISTRATION RECALLS (1977–81)

Bureau	Fiscal year—				
	1977	1978	1979	1980	1981
Foods	169	209	141	193	138
Drugs	350	336	[1] 692	219	188
Medical devices	207	342	342	170	217
Veterinary medicine	110	153	58	[2] 233	44
Biologics	18	15	12	22	43
Radiological health	34	61	45	27	28
Totals	888	1,116	1,290	864	658

[1] DESI.
[2] DES.

There have been 30 pacemaker recalls in the 10 years between 1972 and 1982. Appendix D summarizes the recalls ordered, number of units involved, manufacture, and problem forcing the recall.

C. The Medical Device Amendments of 1976

Until 1976, the FDA's authority to protect consumers from harmful and unreliable medical devices was severely limited. Existing authority was limited to provisions of the 1938 Federal Food, Drug, and Cosmetic Act authorizing action only if a defect was discovered after a product was in use. There was no requirement for premarket approval of medical devices. Moreover, the FDA had to bear

the burden of proving the product was in fact dangerous or fraudulent.

In March 1975, the General Accounting Office, in a report to the U.S. Senate Government Operations Committee, accused the FDA of laxity in regulating heart pacemakers. The GAO noted the FDA had failed to monitor the recall of devices blamed in at least seven deaths, failed to assure the safety of pacemakers, exposing users to unnecessary health risks. The GAO broadly indicted the FDA for its ineffectiveness in handling the recalls of 22,310 pacemakers manufactured by four companies.

In April, the Senate passed, 88 to 5, legislation to give the FDA power to require the same kind of standards for safety and effectiveness for medical devices that the agency requires for drugs. The House, however, differed, action pending the report of the special "Committee on Experts in Medicine and Technology" assembled by the DHEW to assess the potential harm.

In 1976, the committee, chaired by Dr. Theodore Cooper, then the Director of the National Heart and Lung Institute, issued a report identifying 10,000 verifiable injuries directly related to medical devices in the preceding 10-year period, 751 of the injuries reported were fatal.

On May 28, 1976, Congress enacted the Medical Device Amendments of 1976 (Public Law 94-295). The law was carefully drawn in an attempt to avoid the adverse effects attributed to the role of drug regulation in the United States. Control was imposed only over the industry, not over the medical community, and specific provisions were incorporated to eliminate delays in certain regulatory considerations.

The law requires DHHS provide for the classification of medical devices intended for human use based upon their safety and effectiveness as follows:

(1) Class I includes devices not purported to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, and do not present a potential unreasonable risk or illness or injury, and for which general controls are sufficient.

(2) Class II includes devices for which it is necessary to establish a performance standard to provide reasonable assurances of their safety and effectiveness; and

(3) Class III devices for which there is insufficient information for the establishment of a performance standard to provide reasonable assurances of their safety and effectiveness, are purported to be for a use which is of substantial importance in supporting, sustaining, or preventing impairment of human life or health, or present a potential unreasonable risk of illness or injury.

In addition, the legislation:

—Authorizes the Secretary to establish a performance standard for class II devices.

—Requires premarket approval for class III devices and establishes procedures for such approval.

—Places devices intended for human use which were not placed in interstate commerce before enactment of the amendments in class III.

—Authorizes the Secretary to ban devices presenting a substantial deception or a substantial risk of illness or human injury under certain circumstances.
—Authorizes the Secretary to notify all persons necessary under the circumstances to eliminate the risk presented by a particular device.
—Authorizes the Secretary to require a manufacturer of a medical device intended for human use which: (1) Presents a substantial risk of harm to the public health, and (2) was not properly designed or manufactured, to repair, replace, or refund the purchase price of such device at no cost to the person using it.
—Requires every person who is a manufacturer, importer, or distributor of medical devices intended for human use to establish and maintain whatever records the Secretary may direct by regulation.
—Authorizes the Secretary to establish mandatory manufacturing methods for medical devices.
—Provides for an exception from the requirements of this act, under circumstances determined by the Secretary, to permit the investigational use of medical devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.
—Requires the Secretary to provide for public access to information respecting the safety and effectiveness of devices, including information respecting the adverse effects of the device on health.
—Requires manufacturers of medical devices intended for human use to register with the Secretary.

1. PREMARKET APPROVAL

To ease the burden on the FDA and allow the marketing of new devices to continue during the classification process, the law provided (section 510(k)) that new devices could be marketed, notwithstanding the other provisions of the law, pending a determination of "substantial equivalency" with devices in commercial distribution before the enactment of the law.

In practice, this provision requires manufacturers notify the FDA when they plan to market a device they believe to be substantially equivalent to a device that was on the market prior to the enactment of the device amendments in 1976. Critics have charged this procedure, and FDA's generous interpretation of equivalency, has substantially eroded the premarket approval process.

Since 1976, 14 premarket approval applications have been received by the Division of Cardiovascular Devices (appendix E). Twelve hundred section 510 submissions were received by the Bureau of Medical Devices in 6 months (September 1981 to March 1982) last year. Thirteen of the 1,200 (1 percent) were determined not to be substantially equivalent by the Bureau.

In practice, the difference between the section 510(k) procedure and premarket approval is significant. The understanding in the pacemaker industry, for example, is that conventional pacemakers which pace a single chamber of the heart can be approved for

market in less than 4 months under the section 510(k) process. More sophisticated devices judged to require the premarket approval process will require 10 to 18 months before commercial distribution.

2. CLINICAL EVALUATION

As indicated above, the device amendments provide for an exemption to the marketing and approval requirements to permit investigational use of medical devices. Current FDA requirements require the implantation of at least 10 devices at 10 sites followed for 4 months by qualified investigators before approval. Until the completion of that process and subsequent FDA review, the device cannot be marketed.

Given the anticipated market life of a pacemaker—2½ years—the intense competition of the industry, and the fact that salesmen are equally rewarded for investigational and commercial use, it is not surprising at least some firms have attempted to short circuit FDA market approval process by in effect marketing clinical devices.

In 1976, for example, Pacesetter made a commitment to develop "Programalith," a programable pacemaker. In 1977, the manufacturer launched an advertising and public relations campaign, although the product was not approved until 1979.

Another company employed 500 investigators to implant several thousand heart valves while the device was still involved in premarket approval.

A more complicated abuse involves the use of "clinical investigations" as a method for extending the firms market penetration by buying the allegiance of pacemaker professionals. In 1981, for example, one manufacturer solicited "consulting relationships" with a number of physicians. The manufacturer promised the physicians $200 for every pacemaker implanted and suggested the relationship would be reviewed in a year "to see how it should proceed."

Under the terms of the arrangement, the $200 fee would have been a bonus (in addition to the normal rewards associated with pacemaker operations) for assisting the firm establish a "data base."

"I know that any kind of consulting arrangement can become a very sensitive issue when some people interpret any remuneration as a payoff for using a particular company's products," the president of the company wrote one physician. "Please let me assure you that this isn't the case in our instance, as we genuinely need your help. I also recognize that $200 per pacemaker is not much in this day and age, but it does represent a substantial amount to a small company just getting started like ourselves. We can make these payments in whatever manner you see fit. If you prefer that it be made to the hospital, to a fund, partial sponsorship of a resident, or paid directly to you as an individual; we have no preference and will do as you instruct."

Another abuse related to the attempt to promote devices before they have been tested and approved as safe by the FDA. In December 1981, for example, a competitor of Pacesetter informed the FDA the firm was abusing premarket approval procedures. "A few

days ago," the director of regulatory affairs of Intermedics wrote to the FDA, "we talked about the tact taken by Pacesetter Systems, Inc., in promoting their AFP pulse generator at the American Heart Association Convention in Dallas, Tex., during the week of November 16, 1981. Mr. Schwartz was so concerned about the matter that he obtained pictures of the booth, one of which is enclosed. Note that the 'AFP private showing room' was in the general exhibition area where anyone attending might gain access. By virtue of the fact that the AFP is a DDD pacer, which has not been approved for commercial distribution by the FDA, I would assume promotion in this manner to be inappropriate. If I am correct in my assumption, please advise me."

The FDA responded a month later that there is a narrow line between promoting investigational devices and encouraging the development of new devices. "There is a legitimate need for manufacturers to be able to describe devices and disseminate scientific and technical information about them in order to obtain clinical investigators to conduct clinical investigations," Dean Barlow of FDA's Division of Compliance wrote to Intermedics. "Generally, this includes scientific papers intended to convey technical or scientific information about a device. This display of technical information and engineering drawings or the description of an investigational device at a scientific convention—as long as the materials used indicate that the device is 'for investigational use only'—is also reasonable."

Two months later, the FDA received a copy of a Pacesetter press release (appendix F) on the AFP pacemaker that, in the judgment of Mr. Rahmoeller of FDA's Bureau of Medical Devices, "appears to be promotion by the company since nowhere do they mention that this (product) is not yet available, even for clinical investigation." Mr. Rahmoeller concluded with the belief that Pacesetter was promoting the device with the intent of making it available to physicians as an emergency use device (appendix G).

The encouragement of "emergency use" of unapproved devices in this fashion has ample precedent in the pacemaker industry. Some elements of the industry rely on the critical time and judgment elements of an emergency situation to short circuit the approval process. In one instance, a device approved for market this spring had 331 "emergency use" implants vesus 302 implants carried out within the clinical investigations protocol.

Chapter 5

COMMITTEE ACTIVITIES

An April 1981 article in the Philadelphia Inquirer first brought the problems associated with pacemakers to the committee's attention. The Inquirer focused on the role of the pacemaker salesmen and their relationships to the physicians who implant these devices. Questions of cost and utilization were raised as well as allegations of kickbacks, rebates, lavish entertainment, and other inducements to do business.

A. The Garman Letter

In September, Senator Chiles, ranking minority member of the committee, received a letter from a constituent complaining of the warranty associated with a defective pacemaker. The constituent, Mrs. Madeline Garman, indicated the firm had not honored the warranty provision of the pacemaker, and that the costs were being passed on to medicare.

In reviewing Mrs. Garman's hospital bills, committee staff found she was admitted to Memorial Hospital in Sarasota, Fla., on December 26, 1978, and released 15 days later. Her condition was diagnosed as intermittent heart block. A pacemaker, manufactured by Amtech, was inserted. The pacemaker (generator and leads) accounted for $2,960 of the total $5,426.85 billed by the hospital for the procedure. All but $144 of that total was paid by medicare.

In addition, Mrs. Garman received bills for $885 from her surgeon for implanting the pacemaker; $165 from the anesthesiologist; and $385 from her personal physician. Total cost associated with the pacemaker equaled $6,859.

On May 13, 1981, Mrs. Garman was readmitted to Memorial Hospital. The admitting diagnosis was stated as "replacement of pacemaker pulse generator." Cost associated with the replacement generator (supplied by Intermedics), accounted for $3,905 of the hospital total, $1,000 more than the original pacemaker furnished by Amtech 2 years before.

Despite the fact that 8 years remained of the 10-year warranty supplied with the original device, 90 percent of the total $5,556.61 replacement cost was borne by medicare. Copies of Mrs. Garman's invoices and medicare benefit records are included at appendix H. Total charges associated with the two operations borne by medicare exceed $12,000.

B. Investigational Activities

In intervening months since the receipt of Mrs. Garman's letter, committee staff have reviewed media reports, technical papers, and professional journals concerning the development of pacemakers

and problems associated with their use. Corporate reports, professional abstracts, and the reports of market analysts have been obtained and reviewed, as well as the files of four Government agencies—the Food and Drug Administration, the Federal Trade Commission, the Veterans Administration, and the Securities and Exchange Commission. With the assistance of the General Accounting Office, staff reviewed a sample of invoices from 2,500 pacemakers implanted in a 27-month period.

Staff have interviewed pacemaker experts across the country, responsible government officials, physicians, salesmen, former salesmen, and manufacturers.

Staff learned the problems present in the pacemaker field are notorious and of long standing. Despite this awareness, the nature of these problems identified, and program implications identified by the various agencies reviewing pacemaker abuses was frequently not communicated to other agencies sharing oversight responsibility for pacemaker purchase and utilization. All of the investigations conducted appear either more limited than the circumstances would seem to warrant or were abandoned for reasons unknown. Only the Veterans Administration's audit resulted in meaningful reform. Of all the agencies sharing oversight responsibility for the pacemaker industry, the activities of the Department of Health and Human Services, the principal purchaser of pacemakers through its Health Care Financing Administration, have been most limited.

The occurrence of the abuses appeared to result from the correlation of three fundamental forces: (1) The permissiveness of the medicare cost-based reimbursement system, (2) the laxity of oversight and enforcement activities, (3) the symbiotic relationship of pacemaker physicians and salesmen. There is no apparent fear of prosecution in the pacemaker industry for violations of law. As one salesman told the committee, "there have been rumors of a crackdown on the industry for years. I never thought I'd see the day until now."

At the conclusion of our inquiry, faced with a staggering array of abuses, persistent allegations of criminality, and the potential of significant losses to the medicare program, staff arranged to validate results by "buying" pacemakers in two States—California and New York. In both cases, staff represented themselves as the agents of a cooperating geriatric facility interested in establishing a health maintenance organization. Both cooperating agencies were indirect purchasers of pacemakers, dependent on others for the selection and implantation of these devices. Committee staff presented this situation to salesmen with the question of what benefit would result from establishing a direct purchase relationship.

The initial buying test was conducted in California. Subsequently, after communicating preliminary observations to the chairman, a second test was structured in New York to test the pervasiveness of the practices identified in California. The New York interviews were filmed and recorded by staff.

In both States, staff interviewed salesmen representing firms controlling 90 percent of the domestic pacemaker market. In all cases, the activity consisted of a simple phone call from staff expressing interest in direct purchase and a resultant interview.

C. A Pacemaker Primer

Several basic tenets emerged from the experience, the preceding interviews and research:

Comparability of devices.—By every indicator, there are no significant differences between the pacemakers manufactured by the leading companies. In the words of one salesman, "Any one of five pacemakers is excellent. I wouldn't hesitate to put any one of them in my mother." Most manufacturers have the same basic products and accessories.

Purpose of pacemakers.—Pacemakers by and large are employed to improve the quality of life of the recipient. One expert, Dr. Jerry Griffin of Baylor University, explained it this way, "Most pacemakers demonstrate the same point. Most are not lifesaving. They make a qualitative difference. They make the heart work more effectively." Less than 10 percent of the population is considered pacemaker dependent.

Price.—For the most part, price competition engaged in by the industry is to see who can make the most expensive pacemaker. Beyond that, in the words of a New York salesmen: "The industry is totally unconcerned with price—couldn't care less. Medicare reimburses and they just don't care. God bless them, I love it."

Flexibility.—When it is clear that price is a consideration, significant savings can be obtained. The most frequent response to the question of price was "flexible." Prices negotiated by the committee staff ranged from $2,000 to $4,000 for comparable units.

Markup.—In addition to the manufacturer's cost, a significant markup is added by hospitals—the direct purchasers. Markups range from 50 to 150 percent. One instance was found where the hospital tripled the cost of the pacemaker. Since in most cases the pacemaker is either left at the hospital on consignment or brought to the operating room on the day of the operation, it is difficult to see how even a 50-percent markup can be justified.

Profitability.—Pacemakers and related medical procedures are immensely profitable. Most of the manufacturers show a gross profit in excess of 50 percent. "We don't have a cash-flow problem," one salesman said. "Year after year, our operation is not only profitable, but it generates dramatic positive cash flow. It's nice for me," he continued, "because I don't get phone calls from accounts receivable people all the time. Realistically, and I'm not supposed to tell you this, but realistically they don't even question things that are under 6 months."

A second saleman was equally proud:

> The company itself is only 7 years old and it's totally debt free, which I feel in this day and age of high interest rates, is totally remarkable. Debt free, $150 million in America last year, and this year they are projecting $210 million. That's a good job. So it's a 7-year-old company, tremendously diversified, very, very, very sophisticated equipment and we're No. 2, Medtronics is No. 1, they've been around for 25 years.

Politics of medicine.—The number of physicians implanting and following pacemakers has mushroomed. In the words of one Boston

physician, "Physicians quickly learn they'll earn big bucks if they put a pacer in." No one knows how many physicians are implanting pacemakers. Best estimates indicate the number has tripled in the last 4 years.

Much of the recent growth reflects the movement of cardiologist, from a consulting role, to direct implantation. A saleman described the motivating factor as follows:

> I was in this business 5 years before I learned. I thought doctors were something special until I started hanging around the doctor's lounge. They're no different from anybody else. It takes years before they can start earning. And then they want to make as much as they can.

The competition resulting from the influx of pacemaker physicians has resulted in an intense conflict between surgeons and cardiologists. A saleswoman, on learning a cardiologist, cooperating with the committee, was considering direct involvement, said:

> The status in New York now, and especially in ——— Hospital, is that doctors will fight him to the last drop of blood. There are about 18 surgeons who do pacemakers.

The physician/salesman relationship.—The physician and salesman relationship is the heart of the pacemaker industry. Since there are no significant differences in the products, and cost is irrelevant, the decision on which pacemaker to buy comes down to the relation between the doctor and the sales representative, the service and sales inducements offered.

Not surprisingly, a primordial sales environment has evolved. Salesmen, physicians, and regulators interviewed by the committee describe the pacemaker industry as "intensely competitive," "dog-eat-dog," and "filthy."

One New York salesman put it this way:

> There isn't much a pacer salesman don't do. And, if you can think of it, and we don't do it, we will start. That's the name of the game. Every salesman will do the same thing we are doing. Absolutely. You're telling somebody what to get, and as a result some salesman is going to get a commission. He's going to lay out whatever he has for you. If he doesn't, he's making a big mistake because somebody else will. We all have basically the same equipment. * * * It comes down to service.

The salesman/physician relationship.—Despite the dependence of the physician on the pacemaker salesman or maybe because of it, salesmen do not, in general, have a high opinion of pacemaker physicians' knowledge, ability, or motivation.

The following statement, taken from one salesman, is illustrative:

> There are a lot of doctors that just can't figure it out. They are great with cardiology. They are great with medicine. They just don't understand pacing.
>
> Every doctor has a small number of wire problems (problems related to the placement of the pacemaker electrodes during surgery). I know one doctor who told me that his

problem with dislodgment rate with wires was 35 percent. I still don't understand how he gets referrals.

Most surgeons can put pacemakers in. In terms of programing them, a surgeon is really not qualified to say this patient should have a heart rate of 95 beats a minute, this other one should have a heart rate of 60.

The salesman.—Pacemaker salesmen are employed either on salary plus commission, or hired as independent representatives with a percentage of sales. There are about 400 pacemaker salesmen in the country. Because of their importance to the industry, successful salesmen are bought, pirated, and lured from company to company. One salesman identified by the committee had worked for six companies in the space of 4 years. Salaries of $50,000 are considered modest. Average income is said to exceed $100,000 a year. At least some representatives on a percentage are said to earn more than $1 million a year in sales commissions.

Medicare.—Pacemaker firms and salesmen are acutely aware medicare pays for the vast majority of their services and equipment. They are particularly adept at manipulating the program. Several salesmen indicated this knowledge, and ability was the key to their success.

Virtually, every salesman interviewed volunteered to come in and explain the medicare program, set up medicare reimbursable monitoring clinics, train personnel, and provide billing guidance. A couple were even more creative. One arrived with the medicare schedule of allowable charges for followup care. A second suggested, given medicare's reimbursement procedures, it would be to the agencies' advantage to purchase the most expensive devices possible.

"There's one factor that a lot of doctors and hospitals take into consideration," he said, "and that it is reimbursed eventually and it goes into building a base, a rate base. If you buy cheap, it's almost impossible to upgrade. One thing to consider is, if you're dealing with someone who can carry the float, you might want to start out using the expensive pacemakers. It's a clinical decision, but clinically what are you really getting for more money? One thing you would get for more money is establishing a higher reimbursement rate."

"You might want to start out using expensive pacemakers . . . One thing you would get for more money is establishing a higher reimbursement rate."

Chapter 6

CURRENT PROBLEMS

A. Performance

Despite significant improvements in pacemaker generator longevity, performance problems remain. Current voluntary reporting requirements make it virtually impossible for the FDA to monitor pacemaker performance effectively.

Between 1972 and 1975, there were over 24,000 recalls of pacemakers by the manufacturers (about one-fifth of all manufactured during that time). The primary defect was "pacemaker runaway" caused by leakage of bodily fluids into the device (Medical Device Amendments of 1975 hearings). The defects were said to have resulted in 31 deaths and 1,300 emergency removals. Between 1976 and 1977, almost 35,000 pacemakers were recalled, most of them by a single manufacturer—Medtronic.

Since that time, with the introduction of lithium chemistry as a source of power, the number of recalls has diminished significantly. The FDA recalled about 15,000 units in the 5 years between 1977 and 1982, 9,000 of these, however, were recalled within the last year, supporting the argument of some pacing experts, that lithium chemistry is just now entering its critical period. Others remind the consistent historical finding is that pacing systems fail well before the life expectancy period set up by manufacturers.

Despite the optimistic longevity forecasts associated with the development of lithium chemistry as a power source, the rate of explant appears to be the same. In part, this is because over one-half the pacemaker replacements are necessitated by electronic and lead malfunctions unrelated to the power source. According to some experts, even with a perfect power source, some 20 to 30 percent of the patients will require another operation within 3 years.

Complicating matters further is that there are at least five lithium chemistries and probably eight manufacturers who use one chemistry or another giving some 40 variations. Lithium cells are highly complex in design, construction, and their chemical properties. No two cell manufacturers construct their cells in the same fashion, even when using the same lithium chemistry. The chemical properties in one batch may differ from the next batch of cells.

Because of the complexity of pacemakers, and the rush to market these units, it is not surprising that every manufacturer puts out a lemon from time to time. The worst recent example is said to be American Technology's lithium-powered unit that had a 50-percent failure rate within a year. ARCO had similar problems with its lithium units, leading to that company's decision to withdraw from the industry.

The continuance of these problems is further demonstrated by recent reports of difficulty associated with the new, highly sophisticated pacemakers being manufactured by the industry leaders, Medtronic and Intermedics. Both appear to be fundamentally flawed. The Medtronic device, it is said, could result in a variable reverse flow of blood, forcing blood from lower to upper chambers. The Intermedics device could result in atrial fibrilation.

The most significant performance question in the industry at the moment relates to the use of polyurethane insulated leads. Polyurethane leads were developed because they tend to be smaller in diameter than other leads. They take less space in the vein. Because of their size and the slippery nature of the material, it is possible to insert two leads (when pacing both chambers) in a single vein, simplifying the process enormously.

Several recent reports indicate polyurethane leads are developing fissures. If true and the reports are systemic, the concern is that the polyurethane jackets could rupture and expose the wire. If that occurs, the lead may corrode and short. A reoperation would be necessary, and pacer-dependent patients would be at peril.

Heightening the concern is the fact that replacement of leads requires a complete operation similar to the initial implant. It is more time-consuming, risky, and expensive than generator replacements. Since there are now about 60,000 polyurethane leads in place, the hazard appears significant.

FDA files already contain several incidences of failure associated with these leads. In one case, a physician at the University of California noticed the pacemaker in one of his patients was failing. On examination, "the lead was found to have resistances that varied suggestive of insulation break. When pressure was applied, the polyurethane tubing separated, exposing the uninsulated coil."

In addition to failure of the pulse generator and its electrodes, significant problems have been noted with related devices. Over 15 percent of the 65 programers used in various Chicago institutions were found to have malfunctioned for reasons not related to battery or power supply. These malfunctions were said to have resulted in unintended rate changes or increases in the output of the pacemaker. In some cases, the result was a failure to program the pacemaker properly.

The frequency of pacemaker failure is difficult to assess. For the most part, the FDA is dependent on information voluntarily supplied by the manufacturers. A secondary source is the FDA's device experience network (DEN). The DEN is an information system which collects, stores, and retrieves reports of problems in medical devices voluntarily reported from all sources of device experience.

Copies of DEN reports related to pacemakers are appended at I. In general, the network is a useful, if limited source of information. The principal limitations of scope, coverage, and voluntary reporting make it nearly useless for predicting failures.

For the most part, the FDA must rely on performance information supplied by manufacturers. The accuracy of this information is limited by:

Its voluntary nature.—Manufacturers have proven reluctant to submit failure reports that might limit future sales or admit liability. Consistently, to the extent they are available, professional

sources have reported failure rates several times greater than manufacturers claim. The manufacturers reluctance is understandable. Based on recent court history, one pacemaker failure could cost the manufacturer $10 million in legal fees.

Scope.—To the extent that manufacturers report failures, they only report those failures which result from an analysis of returned products. Most defective devices are discarded and never returned to the manufacturer.

Timeliness.—The most consistent failing of manufacturers noted on the FDA inspection reports reviewed by staff related to the timely review of defective devices. In many cases, the devices were never analyzed to determine failure cause. In other cases, the analysis was limited to preserve what might be evidence in an anticipated litigation.

The following examples were gleaned from the FDA's files:

—In October 1981, an attorney in Texas informed the FDA of a manufacturing defect with CPI's "microthin" pulse generator. Seal screws were said to be too short to make contact with the lead terminal pin and to assure electrical capture. An FDA investigation leading to a subsequent recall (appendix J) found 15 reports to the manufacturer identifying the problem. Yet as the FDA responded to the attorney on October 26, 1981 (appendix K), "the FDA was neither aware or informed by CPI of the problems with the setscrews or any action taken by the firm."

—In December 1981, FDA was informed by a consumer that an Intermedics pacemaker was not meeting its longevity projection. A theoretical market longevity of the pulse generator had been estimated at 10 to 16 years, depending on level of operation. In practice, the device appeared to have a useful life of 3 to 5 years. Investigation by the FDA found that 4,000 of the devices had been implanted. Intermedics had been informed of the battery malfunction in January 1981 by the subcontractor. Subsequent investigation by Intermedics confirmed the problem, leading to technical advisories to salesmen (appendix L) and implanting physicians in October 1981. But the FDA did not learn of the problem until 2 months later and was never notified of the problem by the manufacturer (appendix M).

PACEMAKER REGISTRY

In 1974, the FDA initiated a pacemaker registry in an attempt to provide timely information on the problems of pacemakers. The purposes of the registry were to monitor pacemakers pulse generators and lead performance, identify unexpected or catastrophic failure modes, identify reasons for pacemaker removals, assess patterns of use, and provide timely data on use to regulators, physicians, and patients.

The registry was funded as a pilot project by the FDA for 6 years. Total cost of the program equaled $985,134. (A yearly cost summary is appended at N.)

The registry utilized data acquired from five pacemaker centers: Pacemaker Center, University of Southern California School of Medicine; Rush Presbyterian, St. Luke's Medical Center; Toronto General Hospital; Montefiore Hospital and Medical Center; and

Pacemaker Center, Inc., Beth Israel Hospital. Data was stored and processed at the Pacemaker Center in New Jersey and collated at the University of Southern California.

In the 6 years of the registry's existence, 4 percent of the 3,189 pacemakers contained in the registry were reported to have failed in a catastrophic, life-threatening way. Seven fundamental problems with pacemakers were identified by the registry, and reported to the FDA, before physicians were notified by the manufacturer.

In the first 2 months of 1982, problems with six pacemaker models were identified by the registry. Table 5 below indicates the manufacturer, model number, and failure mode reported by the registry.

TABLE 5.—PACEMAKER FAILURES IDENTIFIED BY FOOD AND DRUG ADMINISTRATION REGISTRY, JANUARY AND FEBRUARY 1982

Manufacturer and model number	Number in series	Number failed	Implant duration (months)	Failure mode (clinical) [1]
CPL, 601	28	1	51	Rate decrease.
Coratomic, L-500	54	1	42	Do.
Cordis:				
233D	17	1	([2])	Unable to program.
334A	49	1	12	Sensing malfunction.
Intermedics, 253-01	37	1	24	Do.
Medcor, 3-70C	93	1	48	Rate decrease.

[1] Each verified by bench test to reflect a pulse generator malfunction.
[2] 1 day.

Despite the apparent success of the registry, it has been discontinued due to fiscal pressures. Initially, funding was reduced to about $45,000 per quarter. In March 1982, the contract with the five pacemaker centers was allowed to lapse.

Recent examples of impact of pacer-related performance problems from FDA files include:

—In November 1981, Mrs. Peter Contardo of Trenton, N.J., had a Medtronic pacemaker implanted because her heart was "skipping." According to her husband, the wound was slow in healing and she was tired all the time. In January she experienced severe pains in her chest and back. She was spitting blood. After a series of tests, the device was removed. Mrs. Contardo subsequently spent 24 days in the hospital at a cost to medicare of about $30,000. When Mr. Contardo tried to obtain the pacemaker to ascertain the cause, he found the pacemaker and leads had been discarded. No one had made an attempt to evaluate the device's performance, report the incident to the manufacturer, or the FDA. Meanwhile, the woman has developed thrombosis and traumatic neurosis.

—In November 1981, the FDA initiated an investigation of a Pacesetter Systems, Inc., pacemaker after testing at the Goddard Space Center indicated the firm appeared to be using a 5-year battery in a pacemaker it guaranteed for 10 years. In attempting to quantify the problem, the FDA found substantial deficiencies in Pacesetter's complaint-handling procedures. "These deficiencies," it was noted, "made it difficult to deter-

mine whether all failures had been followed up and/or documented."

—A doctor reported a Cardiac Pacemaker, Inc., pacemaker caused death when another doctor programed the pacemaker too low. The reporting physician considered the fact that the pacemaker could be programed at such a low level to be a safety hazard.

—A lithium pacemaker manufactured by Cordis, with an anticipated life of 10 years, failed 7 months after being implanted in September 1979, endangering the life of the patient. A second Cordis pacemaker with an 8 to 10 year warranty failed after 4 years.

—Two patient deaths reported in 1979 were said to be caused by a "runaway" CPI pacemaker.

—A 66-year-old man lost consciousness while driving his automobile when the pacemaker's electrical system failed due to a faulty solder joint.

B. Cost

Payments made for pacemaker implanting and followup procedures under medicare's "reasonable cost" guidelines are excessive.

The following cost elements are incorporated into the total pacemaker cost borne by the medicare program and ultimately, the American taxpayer: Manufacturing and marketing costs for pulse generators; leads and associated equipment; hospital markup; hospitalization; operating room and related costs; professional fees, including referring physician and cardiologist; surgeon's fee; followup; and monitoring.

Current best estimates indicate the total cost associated with each pacemaker implanted in 1982 to be $10,000 to $17,000. Total 1982 expenditures are estimated in excess of $2 billion.

At every level, our investigation indicates costs are excessive and profit is inordinate. Followup and monitoring costs will be discussed separately. With regard to the remaining cost elements are findings as follow:

LIST PRICE

The manufacturer's list price includes cost of material and components, general administration, marketing and sales, research and development, tax and profit.

The average pacemaker currently costs between $600 to $900 to manufacturer, and is sold to the hospital for $3,000 to $5,000. In practice, the principal difference between product cost and sales price consists of marketing and profit.

Given the essential equivalency of the devices and medicare's insensitivity to price, it is not surprising that marketing costs are significant. A former corporate officer of one firm informed the committee that nearly 50 cents of every dollar of the pacemaker list price was dedicated to marketing activities. Half of that total—20 to 30 percent of the list price—was paid by the firm as a sales commission to its sales representatives. The remainder is divided between direct marketing, advertising, travel (for sales representa-

tives and doctors), clinical investigations (seen as a marketing tool), and more innovative sales inducements.

Although the percentages may vary and the specific arrangements with the firm's sales representatives differ, the general pattern is consistent. Pacemakers tend to be immensely profitable enterprises.

Market sources estimate corporate gross profits for most pacemaker firms in excess of 50 percent of sales. Two firms, Intermedics and Medtronic, have an estimated gross profit of 68 percent and 63 percent. Profiles of Intermedics and Medtronic, and another firm, Cordis Corp., can be found in tables 6, 7, and 8.

TABLE 6.—INTERMEDICS, INC., CONSOLIDATED OUTLOOK, 1980–82 [1]

[Dollar amounts in millions]

	1980	1981	1982
Pacing systems	$82.5	$104.5	$120.0
Intraocular lens	9.5	12.5	15.5
Carbomedics	11.0	13.0	18.0
Surgitronics	2.0	7.0	9.0
Other		4.0	10.0
Total revenues	105.0	141.0	172.5
Cost of goods sold	35.0	46.2	55.7
Gross profit	70.0	94.8	116.8
Selling	30.0	40.0	48.8
General and administrative	13.0	18.0	22.4
Research and development	4.5	6.5	7.8
Interest expenses/other	3.0	5.5	7.0
Pretax income	19.5	24.8	30.8
Taxes	8.3	10.5	12.9
Net income	11.2	14.3	17.9
Earnings per share	1.30	1.65	1.95
Percent of sales:			
Cost of goods sold	33.3	32.8	32.3
Gross profit	66.7	67.2	67.7
Selling	28.6	28.4	28.3
General and administrative	12.4	12.8	13.0
Research and development	4.3	4.6	4.5
Pretax income	18.6	17.6	17.9
Net income	10.7	10.1	10.4
Tax rate (percent)	42.6	42.5	42.0

[1] Kidder, Peabody & Co., Inc. estimates.

TABLE 7.—MEDTRONIC, INC., CONSOLIDATED OUTLOOK, 1980–82 [1]

[Dollar amounts in milions]

	1980	1981	1982
Pacing systems	$231.8	$275.0	$320.0
Other cardiovascular	14.1	19.5	24.0
Nuclear imaging	15.3	25.0	35.0
Neurological	8.0	12.0	16.0
Other	1.1	2.0	3.0
Total revenues	270.4	332.0	398.0
Cost of goods sold	98.3	123.0	145.1
Gross profit	172.1	209.0	253.0
Research and development	19.1	23.0	28.0

TABLE 7.—MEDTRONIC, INC., CONSOLIDATED OUTLOOK, 1980–82 [1]—Continued

[Dollar amounts in millions]

	1980	1981	1982
Selling, general and administrative	99.7	119.5	143.0
Interest expenses	3.8	5.0	5.0
Interest income	(3.7)	(5.0)	(7.0)
Pretax income	53.2	66.5	84.0
Taxes	14.5	22.0	27.5
Net income	38.7	44.5	56.5
Earnings per share	2.52	2.85	3.55
Percent of sales:			
Cost of goods sold	36.4	37.0	36.5
Gross profit	63.6	63.0	63.5
Research and development	7.1	6.9	7.0
Selling, general and administrative	36.9	36.0	38.0
Pretax income	19.7	20.0	21.1
Net income	14.3	13.4	14.2
Tax rate (percent)	27.3	33.0	32.7

[1] Kidder, Peabody & Co., Inc., estimates.

TABLE 8.—CORDIS CORP., CONSOLIDATED OUTLOOK, 1980–82 [1]

[Dollar amounts in millions]

	1980	1981	1982
Pacing	$71.8	$79.5	$94.5
Angiography	23.7	30.0	37.5
Instrumentation	8.3	10.0	12.5
Neurosurgical	5.0	8.5	8.0
Immunology	1.3	2.0	3.0
Other	.9	1.5	3.0
Total revenues	109.0	129.5	158.5
Cost of goods sold	51.5	53.5	63.5
Gross profits	57.5	78.0	95.0
Research and development	13.4	15.5	19.0
Selling	23.0	27.5	33.0
General and administrative	13.5	17.0	20.0
Operating income	7.8	16.0	23.0
Interest expense	5.8	8.0	9.0
Interest income	(1.3)	(1.5)	(.5)
Other	.4	.5	.5
Pretax income	2.9	9.0	14.0
Taxes	1.2	3.3	5.8
Equity in Cordis Dow	1.1	(1.0)	1.0
Extraordinary credit	.4	.5	
Net income	3.2	5.2	3.4
Earnings per share	1.26	2.00	3.55
Percent of sales:			
Gross profits	52.8	58.6	60.0
Research and development	12.3	12.0	12.0
Selling	21.1	21.2	20.8
General and administrative	12.4	13.1	12.6
Operating income	7.0	12.4	14.5
Pretax income	2.7	6.9	8.8
Equity in Cordis Dow	1.0	.8	.8
Net income	2.9	4.0	5.9
Tax rate (percent)	41.4	37.0	40.0

[1] Kidder, Peabody & Co., Inc., estimates.

Further evidence of the profitability of pacemakers was gained by our interviews with pacemaker salesmen. Most salesmen freely admitted there is considerable "flexibility" in the list price. Once it became apparent that price was a critical condition of the sale, every manufacturer expressed a willingness to reduce the price.

Some manufacturers extended the offer to include devices marketed in Europe where prices are a factor. "We have what we call a price-sensitive pacemaker," one salesman said. "They are not listed on here (the price list), but I can get you a programable pacer good for 5 to 7 years, for about $2,000, a nonprogramable for $1,650.

A second suggested we take advantage of a "fire sale" on obsolete pacemakers. The salesman suggested perfectly good discontinued pacers listing for $3,500 could be made available at $1,500.

The following approach was typical:

Staff: "What are we talking about in terms of cost?"

Salesman: "The top of the line psychological pacer costs about $4,100."

Staff: "How about the bottom of the line—the fixed rate pacers?"

Salesman: "They're used infrequently. They didn't even put it on the price list. It's about $2,800."

Staff: "Would you give us an approximate bid price, a ballpark figure for, say 30 patients?"

Salesman: "As a blanket statement across the board, I would say that a discount of 15 percent would be more than realistic and probably be the minimum discount you could expect."

In all, we were offered pacemaker prices ranging from $1,000 to $5,000. Discounts were offered by representatives of every manufacturer we saw. The amount of the discount ranged from a low of 10 percent to a high of 50 percent on specific items. The most common discount offered was 15 percent. In most cases, the price quoted with the discount included telephone transmitters and receivers for monitoring every patient, pacemaker programers, analyzers, and a host of other accessories thrown into the bargain as "free" extras.

HOSPITALS' MARKUP

Despite the apparent excessive cost of pacemakers, it is widely agreed the biggest cost in pacing is not the pacemaker, but the related surgical intervention. Costs associated with pacemaker insertion include hospital stay, operating room costs, pharmacy charges, related professional fees (anesthesiologists, cardiologists, etc.), and pacemaker markup.

Hospitals commonly mark up pacemakers from 50 to 150 percent, despite the fact that there is no apparent correlating hospital cost associated with the unit. Pacemakers are generally not purchased by the hospital until the time of their use. Pacemakers are either left on consignment or delivered by the salesman the day of the operation.

Most generally, in the words of one salesman, hospitals "turnkey" the pacemaker cost: "They double it. If we sell it to you for $3,500, they charge $7,000."

A New York salesman told us he knew of a hospital in Long Island that tripled the retail cost.

> I had an irate phone call from a gentleman who was insured by Equitable because he wondered how—he was on a second pacemaker—he was wondering why when his first one had only cost $6,000 his new one cost $17,000. I said wait a minute. Your first one, we billed them $1,800 or $1,795, and this one we billed them $2,300 or $3,200, or something. They marked it up a lot and his insurance company just paid it.

With the assistance of the General Accounting Office, staff identified and reviewed a random sample of 2,500 pacemakers implanted in a 27-month period. Hospital stays associated with pacemaker insertion varied from treatment and release on the same day (a replacement) to 17 days. Pharmacy charges averaged $200 to $400. Laboratory charges averaged $300 to $500, radiology charges were extremely variable from several hundred dollars to $1,000. Surgeons' fees ranged from $1,000 to $2,500.

Pacemaker charges ranged from $3,000 to $5,000. In many cases the pacemaker cost was buried in the operating room expense and only retrievable on specific inquiry. All of the problems with respect to pacemaker purchase price, hospital markup, and warranty question noted in the committee's investigation were reflected in the invoices. The following eight examples illustrate these problems:

—In December 1980, an 82-year-old woman received a pacemaker for a third degree heart block. The pacemaker cost $830 to make. It was billed to the hospital at $3,395. The hospital billed it to medicare at $4,074. The lead associated with the device was billed to the hospital at $325. The hospital billed medicare $455. In both cases, hospital records indicate the purchase order was cut the day of the operation. Total hospital charges for the procedure, including pacemaker, totaled $7,277. The surgeon charged $1,420 for the implantation. Over 1½ years postoperative care totaled $3,000. Total expenses associated with the pacemaker, implantation, and 18 months postoperative care equals $11,727.

—A 68-year-old man received a pacemaker in February 1981. His admitting diagnosis was bradycardia. The pacemaker he received cost $858 to make. It was billed to the hospital for $3,795. The hospital billed medicare $9,887.41 for the pacemaker procedure, including $4,134 for the pacemaker and $402 for the lead. The surgeon billed medicare $1,200. Six months postoperative care totaled $1,911.50. Total charges to the program associated with the operation and 6 months of postoperative care equaled $13,018.91.

—An 89-year-old woman with third degree heart block received a pacemaker in February 1981. Charges to the program included $3,999 for the pacemaker, $455 for the lead. Total hospital charges equaled $10,214.38. The surgeon charged $1,572. Eight months postoperative care totaled $3,242. Total charges to the program associated with the procedure equaled $15,028.38.

—A 90-year-old woman received a pacemaker in October 1980 after a mild cardiac arrest. The hospital bill for the procedure totaled $9,557.75, including 5 days hospitalization at $500 per

day and a charge of $4,950 for a pacemaker and $300 for the lead. In August 1982, the same pacemaker was offered for sale to the committee at $2,192.40. The lead was priced at $259. The surgeon billed medicare $1,100 for the 1980 implant. One year of postoperative care totaled $2,412. Total program costs associated with this procedure to that point equaled $13,070.

—An 80-year-old woman with the classic pacemaker diagnosis of Stokes Adams syndrome received a pacemaker in 1980. Her hospital bill totaled $9,180.74. The pacemaker was billed at $3,547. The surgeon charged $1,725 for the procedure, 1½ years of postoperative care totaled $2,896. Two abnormalities were noted in the bills submitted to medicare. One involved billing $183 for a lead that was not used in the procedure. The second involved an extraordinary bill of $100 for transtelephonic monitoring. Medicare only allowed $20 of the $100 charge, but the rest was passed on to Blue Cross and the patient.

—A hospital billed $8,971.95 for implanting a pacemaker in a 76-year-old woman with arrhythmia. The surgeon's bill of $1,615 and 8 months postoperative care brought the total associated with the procedure to $14,334.95. Included in the hospital's charges were $6,398.50 for pacemaker and accessories. Among the accessories the hospital billed to the program were a number that were freely offered to the committee—a "miniclinic" (billed at $420), a magnet (billed at $62.50), and a telephone transmitter (billed at $324). Whether or not the hospital paid for the accessories cannot be determined by the available records. Both the "miniclinic" and magnet are devices primarily designed for physician use and of little direct value to the patient.

—A hospital billed $3,656 for replacement of an "exhausted" generator. The bill indicates the patient was treated and released on the same day. Pacemaker costs accounted for $2,900 of the total and surgeon's fees added $650. The entire replacement operation cost $4,306. Although the pacemaker warranty was apparently still in effect, there is no indication the warranty issue was persued.

—Earlier this year a 90-year-old man received his second pacemaker in 3 years. In 1979, when the first pacemaker was implanted, the program was charged $6,262 by the hospital including $2,970 for an Intermedics pacemaker and $330 for the leads. Associated surgical fees added $1,800 to the total, $1,256 of which was paid by medicare, $374 by Blue Cross, and the rest written off by the physician as a bad debt. Total charges for the initial implant were $7,518. Replacement cost for the pacemaker, still within warranty, totaled $12,344, despite the fact the replacement of a pulse generator is uncomplicated and generally can be accomplished without hospitalization. The replacement generator accounted for $4,466.50 of the hospital bill. There was no billing for leads, indicating only the generator was replaced. The replacement generator was also manufactured by Intermedics of Freeport and cost $830 to make. It was billed to the hospital at $3,500. Hospital records reflect a call to the manufacturer verifying warranty provisions were

still in effect. There is no indication a credit against the replacement price verified by the hospital was ever granted or transmitted to medicare. In calling this matter to the attention of Blue Cross and medicare program integrity, the patient's daughter-in-law wrote: "To me this is ripping off medicare, as I do not see a credit for the pacemaker. It is not supposed to be done that way according to the warranty."

SURGICAL FEES

Generally the actual implantation of the pacemaker is done by a surgeon or a cardiologist teamed with a surgeon. Surgical fees for implantation range from $750 to $2,500. Operations average 30 to 90 minutes.

In the view of at least one expert, fees for pacemaker surgery are clearly out of line with comparable procedures. Emanual Goldberg, writing in the journal of pacing professionals, PACE, said:

> Surgical fees are out of proportion to the difficulty of the technique. This seems to be left over from the days of pacing when a thoracotomy was required for most implantations. Also, for a long time patients and third-party carriers may have assumed that the cost of the implanted unit was included in the surgeon's fee. The billings approach three-fourths of the fee charged for repai of an abdominal aortic aneurysm, while the technical difficulty and risk is less than one-tenth that of the vascular procedure.[2]

Other experts and pacemaker salesmen endorsed that concern. "It's a relatively easy procedure and you get a lot of money for it," one salesman said. "Fifteen minutes if everything goes well, if all the X-ray equipment is working properly, the patient got to the OR on time—as the procedure takes you 15 minutes work, and they bill $2,100 between $1,500 and $2,100, for 15 minutes work."

In addition, surgeons are rewarded in a number of other ways detailed in section D kickbacks. Perhaps the most lucrative awards are associated with monitoring section F.

It is clear that the lack of price sensitivity by reimbursement authorities had fed the escalation of costs and encouraged corrupt practices. Low price, "no frill," pacers have as much as one-third of the foreign market, but account for only a small fraction in the United States. Even when the more sophisticated devices are used in Europe they are obtained at a significant price reduction to what is offered in the United States. One industry source estimated the difference at 30 to 40 percent.

REFURBISHED UNITS

In some European countries, pacemakers are refurbished and reused. By definition, a used pacemaker can be anything from a device that has been implanted in a patient for a significant period of time, to one where the package was opened, sterility breached, and the pacemaker never implanted.

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[2] PACE, vol. IV, April 1981, page 280.

In all cases, in America, the pacemaker would either be discarded or returned to the manufacturer, making these devices perhaps the most expensive disposable items in our society. Since the anticipated life of most pulse generators is projected to be greater than 50 percent of those who currently receive pacemakers, the fiscal impact of this policy is significant.

Because of the significant costs associated with pacemakers in a number of foreign countries, pacemakers are refurbished—cleaned, reexamined, tested, operation and useful life estimated, and reimplanted where appropriate.

In Australia, for example, where all pacemakers are purchased by the government, refurbished pacemakers are considered a safe and economic procedure. One study, conducted by Dr. Harry Mond, department of cardiology, Royal Melbourne Hospital, described a review of 83 pulse generators that were refurbished and reused over a 2-year period in Australia. Twelve of the generators were refurbished twice. Only two complications emerged from the process—one resulting from infection and the second from a power depletion.

The major incentive for refurbishing pulse generators was economic. Approximately 20 percent of the generators implanted in the 2 years (1977–78) in Australia were refurbished. It is estimated the yearly cost savings exceed $700,000.[3]

The only apparent experience of reuse in this country was the Minneapolis Veterans Administration between 1978–79. The Minneapolis VA decision to reuse pacemakers was specific to that office and not replicated in other VA sites. Cost savings of this limited experience were estimated at $21,000.

In general, when the question of reuse of pacemakers comes up, the quick response in the field is that the Food and Drug Administration will not allow it. On specific inquiry, a spokeman for the FDA informed the committee to the opposite: "I would prefer it," said Glenn Rahmoeller, Bureau of Medical Devices. "What we want is premarket approval to show the device has been recleaned, resterilized, and document the remaining life. But who's going to do that? The manufacturer isn't. Most units go out so fast, you don't have any real data on it until it's off the market. I'd rather know."

One of the salesmen was more explicit:

> In Europe it's done. They do recycle pacemakers. The manufacturers here don't want anything to do with it. Their reason being that they don't make much money off of it. They make some money because generally the pacemakers have to be sent back to the manufacturers where they are cleaned up because there's protein deposits that build up in the connectors, and in the epoxy, and that has to be cleaned out.

Because of our cavalier controls on explanted pacemakers—many of which are discarded—and the inherent value of the instrument, there are recurrent rumors in the industry that pacemakers explanted are bootlegged out of this country for sale abroad. The oc-

[3] PACE, vol. III, No. 3, May 1980, page 311.

currence of these activities was confirmed by our investigation. The committee did not attempt to assess the prevalence of these practices or their legality. The specific information discovered and the source have been referred to the FBI for investigation.

C. Implantation of Pacemakers

There are no professional requirements with regard to where pacemakers are implanted and who can perform these operations. The absence of these professional requirements, the ease and profitability of the procedure have resulted in inadequately trained pacemaker professionals, overutilization of pacemaker procedures, needless surgery, undue reliance on pacemaker salesmen, and improper cost to the program.

The regulation of professional activities in this country has generally been considered a professional responsibility. Unfortunately, there has been little attention directed at who should implant pacemakers in the United States and where these implantations can safely and appropriately be made.

In Canada, France, and a number of European countries, these professional requirements have been formalized to assure competent implantation, monitoring, and observation. In this country, in the words of Dr. Victor Parsonnet, Beth Israel Medical Center, Newark, N.J., "A person is a pacemaker expert if he says he is."

Pacemakers are implanted in the United States by thoracic surgeons, general surgeons, internists, cardiologists, osteopaths, and others. Many have very limited knowledge of pacemakers and their operation. Some have never witnessed a pacemaker implantation before they attempted the operation. Pacemakers are implanted in settings as various as pacemaker centers located in teaching hospitals, treating, and following thousands of patients a year, and community hospitals that may only implant two a year.

In Canada, by contrast, guidelines for cardiac pacemaker units were established in 1978. A cardiac pacemaker unit is defined by the Ministry of Health as, "a hospital-based clinical unit that is organized, staffed, and equipped to provide all services required for pacemaker implantation and patient followup." The minimum average caseload for a cardiac pacemaker unit was established at 50 procedures per year. This minimum caseload was established to develop and maintain the skills and competence of the pacemaker team. Canadian studies and experience strongly indicate that quality of procedure is closely associated with caseload.

A pacemaker team essentially provides expertise in all mechanical and engineering aspects of pacemaker technology, pacemaker electrophysiology, surgical and cardiac catherization techniques, and the special use of radiological equipment, and the management of complications and emergencies during and after implantation. The team is composed of an experienced surgeon (cardiovascular, thoracic, or general), a cardiologist, an anesthesiologist, a nurse/technician, a radiological technician, a biomedical engineering technologist, and a secretary/technician.

Minimum training for physicians in a cardiac pacemaker unit includes certification in medicine or surgery, plus experience that includes performance under supervision of at least 20 new implants,

20 pulse generators, and 25 temporary insertions. Nursing staff and other professionals are also required to receive appropriate training. There are no such minimum training requirements in the United States. Similarly restrictive standards are required for operating rooms, including the availability of all potentially essential equipment, proximity of coronary and/or intensive care unit facilities.

An April 1982 survey of New England pacemaker practitioners provides a stark contrast. Three-fourths of the 191 physicians responding indicated they implanted less than 50 pacemakers a year. Over 50 percent implanted less than 25 a year. Only half of those responding had received formal training in pacemaker insertion. The other half were either self-taught or learned the procedure from observation.

Fifty-nine percent of those implanting in community hospitals were not surgeons (52 percent cardiologists and 7 percent internists) compared to 46 percent in medical centers. No internists implanted pacemakers at medical centers.

The pacemaker salesman was reportedly always present in the operating room at one-quarter of the community hospitals. The sales representative was at least occasionally present in 83 percent of the community hospital operations. Physicians at medical centers were slightly less likely to depend on salesmen, reporting their occasional presence at about 73 percent of the facilities.

Sixty percent of the physicians practicing at community hospitals responded that the sales representatives' presence was either essential or helpful. Only 48 percent of those practicing at medical centers agreed.

Basic equipment necessary under Canadian standards for appropriate pacemaker implementation was absent from 18 to 66 percent of the facilities. Table 9, below, details the equipment reported to be routinely available in the community hospitals and medical centers responding to the survey.

TABLE 9.—PACEMAKER EQUIPMENT ROUTINELY AVAILABLE IN COMMUNITY HOSPITALS AND MEDICAL CENTERS

[In percent]

	Community hospitals (82)	Medical centers (37)
Fluoroscopy	100	100
Fluoro table	82	94
Defibrillator	98	100
Remote monitor	76	86
EKG machine	76	97
Threshold analyzer	90	100
Multichannel recorder	34	81
Oscilloscope	60	70
Bovie	34	46
Anesthesia machine	60	51
Chest tube set	32	54
Anesthetist	62	54
"Code call" team	39	59
Another physician implanter	35	41

The state of the art is such that implanting pacemakers is now considered a relatively nontraumatic operation, usually done under a local anesthetic, and completed within half an hour. The operation is easy enough, particularly given the financial rewards, that an increasing number of nonsurgeons feel competent to perform it. The pacer is placed under a small pocket formed under the skin on the chest, and a lead is run from it, through a vein to the heart. For this, the usual fee runs from $1,000 to $2,000.

The prevailing attitude is that pacemakers are relatively no-risk operations that pay well. Those two factors and the stimulus of the pacemaker representatives have tended to make implanters somewhat casual about implanting decisions.

In addition to the impact on utilization, needless surgery, cost to the program and risk to the patient, this perception distorts reality. Although the procedure of implanting a pacemaker is relatively simple, the technology of pacing becomes increasingly more complex. The decision on the appropriate modality for the patient's needs requires training and experience. Several of the new pacers have as many as several million programable variations capable of confusing even the most seasoned implanter.

As one physician, Dr. Victor Parsonnet of Beth Israel Hospital in New Jersey, told the committee:

> If I, who have been implanting pacers for 21 years, can become hopelessly confused, where is the doctor who implants one a month.

Most experts agree the American method of pacemakers being implanted in every small hospital and by everyone who has access to fluoroscopy provides inferior patient care to that available in North America and more generally prevalent in Europe. As technology becomes more complex, the odds of improper pacer selection, programing, and placement, because of confusion and misunderstanding, increase. Increasingly, at least some professionals see the need for the development of a specific pacemaker disciplining, with specific training and credential requirements.

The implications of poorly trained physicians and ill-equipped operating rooms on the success of the procedure and the cost to the program are many. None are more graphic than the following example. In 1979, the FDA received a medical device complaint related to the death of a pacemaker patient in Puerto Rico. The autopsy report of the patient described severe lacerations of the left ventricle beyond the damage normally associated with the insertion of a pacemaker lead. After investigation, the FDA concluded the death was caused by the "misuse of the device by the physician involved." The pacemaker design, labeling, and contraindications were deemed appropriate. Death was ascribed to "physician error."

D. Kickbacks

Evidence of kickbacks and other improper inducements associated with the pacemaker industry has existed for more than 5 years. Knowledge of these improper activities is reflected in the working papers of five government agencies, yet the problem persists. From the committee's investigation, evidence and allegations of kickbacks,

bribery, and other improper inducemen to do business are flagrant and inescapable.

THE SEC

In 1977, Medtronic filed a form 8-k with the Securities and Exchange Commission, disclosing improper and questionable payments made in foreign countries in the period from May 1, 1973 to April 30, 1976.

Medtronic disclosed payments of $26,550 paid to officials in two foreign countries for approximately $438,000 in additional business. Medtronic also disclosed "questionable or improper under the laws of that country" payment of expenses for trips for physicians not related to business purpose, Medtronic reimbursed travel, and the donation of equipment to physicians. Payments to physicians approximating $200,000 were identified in trips and equipment over the 3-year period.

Specific bribes to physicians included:

—A 25-percent commission paid to an individual characterized as a distributor. The disclosure indicated the payment was passed on to the physician placing the orders. Payments to the physician totaled $48,500 for orders totaling $194,000 over 2 years.

—Two physicians in another country received discounts totaling $8,000 and a third physician received $400 in cash for a single large purchase totaling $58,000. Payments to hospitals totaled $554,600 in the 3-year period.

—Payments involving off-book accounts and fictitious transactions.

Medtronic indicated these activities had ceased. No improper domestic activities were identified or disclosed. Specific written statements (a business code) forbidding bribery, kickbacks, and political contributions were adopted as a corrective measure.

THE FTC

A year later, the FTC in its investigation of the pacemaker industry, uncovered substantial allegation of bribery and kickbacks. Most of the allegations involved Medtronic's primary competitor, Intermedics. At the conclusion of its investigation, allegations of bribery were said to be referred to the Department of Justice for investigation and prosecution. The Department of Justice indicates the referral was never received. The FTC investigation is detailed in chapter 7.

In July 1982, the Wall Street Journal and Barron's reported a reappearance of the allegations of bribery and kickbacks associated with the pacemaker industry. Most companies involved denied involvement or any impropriety.

The FBI investigation is said to be nationwide and related to violations of the medicare kickback statutes, mail fraud, wire fraud, and general fraud against the Government. Among the allegations under investigation are the following:

—Cash kickbacks.

—Stock or stock options offered to doctors as an inducement to do business.

—Rebates, intended for patients, sent directly to physicians.
—The use of "consultant" agreements as camoflauge for direct payments to physicians for using specific products.

In the committee's investigation, evidence of kickbacks, potential bribery, and other inducements to do business were flagrant and inescapable. Inducements ranged from outright payments of cash to physicians for implanting a particular manufacturer's device, to "replacement credits" tied to warranty provisions, expensive gifts, travel, lavish entertainment, and rebates. Our experience verified the judgment of one former salesman, "The problem is at least some companies are giving money back in many ways."

Kickbacks Defined

Title 42, section 1395 of the U.S. Code defines a kickback as follows:

(a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this subchapter.

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefit or payment.

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person, shall (i) in the case of such statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under this subchapter, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, or conversion by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both.

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or

rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this subchapter, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this subchapter, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than 5 years, or both.

The existing kickback statute, detailed above, was significantly modified, by Public Law 95–142, adopted in 1978. Largely because of the Senate Committee on Aging's clinical laboratory, medicaid mills, and nursing home investigations, the demonstrated impact of these practices on overutilization and increased cost, penalties for kickbacks were extended from a misdemeanor to a felony. The legislative history of Public Law 95–142 is even more specific as to what constitutes a kickback:

> Kickbacks take a number of forms including cash, long-term credit arrangements, gifts, supplies and equipment, and the furnishing of business machines.[4]

Specific evidence of improper inducements found by the committee have been referred to the Department of Justice, the FBI, SEC, FTC, and IRS for investigation. The following examples are typical of the kind of conduct observed.

DIRECT KICKBACK

California salesman for company 14: "Some companies pay physicians $150 for each pacemaker they implant."

Staff: "You mean a physician is going to make that kind of decision for $150?"

[4] H.R. 95-673, page 1008.

Salesman: "You've got to remember some of these physicians implant 10 to 15 a week. That's a lot of money. I'm not saying everyone does it. But it does happen. It's a known fact in the industry."

INDIRECT KICKBACKS

Kickbacks are often disguised as follows:

—Payments of $200 to $20,000 purportedly for "clinical evaluations."
—Use of company credit cards.
—$150 paid by one manufacturer to a Pennsylvania physician for every initial implant of the manufacturer's product.
—Stock offered at reduced prices or stock options of pacemaker firms.
—Payment of $300 to $500 for "unreimbursed medical expenses" of physicians with no requirement of documentation.

Of these mechanisms, stock options are said to be most persuasive. Two firms are said to have been particularly successful with this approach. Commenting on one of these, a salesman for a rival company said:

> They got a big part of their start in sales by selling stock to doctors and they have some nice pockets of business where a group of surgeons or cardiologists have some stock or own a company which has some stock in Intermedics.

The second firm is reported to have offered the following explanation at the point of going public with a stock offering:

> Some doctors don't want to deal with a company unless they are investors in it.

It should be noted that stock ownership by a physician can be either legal or illegal depending on the circumstances of acquisition and amount paid for value received.

TRAINING

Offers of training are freely provided as an inducement to do business. Training suggested ranged from simple inservice on how pacemakers work, to more questionable activities including training personnel in setting up and operating followup clinics, to maximizing the return from medicare, and specific training in the operative procedure provided an inexperienced physician.

With respect to monitoring, salesman 4 said:

> We would supply you with everything that you need. If you needed to train someone I would do that. I've trained many, many, many, and we wouldn't disappear. We just don't do that. We see you through the whole thing until you tell us we don't need you anymore.

With respect to a cooperating physician, salesman 17 offered the following schooling mechanism:

> There are programs that we run for M.D.'s that are involved in pacemakers and want to—either because they are following a large number of patients with pacemakers or want to become involved in the operative procedures to

implant pacemakers—we run educational programs. Obviously it's beneficial to us to train M.D.'s because they look favorably on the organization and it's beneficial to the physician.

We do that on a quarterly basis. Right now, it's limited to six M.D.'s from across the country. The organizational management decides on priorities because there are literally hundreds from across the country who want to participate. That program will be expanded because it's so popular.

Staff: "If we wanted our medical director or someone to become involved in that process, could it be arranged?"

Salesman: "Absolutely. Prioritywise, as we go down the road, should there be a decision to deal with our firm or if that would be an influencing factor, I can guarantee that."

Staff: "The program gives specific guidance advice on the device, how it works, and what patients would benefit?"

Salesman: "Yeah, so they are able to become true experts when it comes to looking at the electrocardiogram and also the operative procedure, so that if there is a problem you know how to bail yourself out."

Staff: "Is there a cost associated with the program?"

Salesman: "There's no cost associated with that."

A more common approach was offered by salesman 16: "I'll arrange to have some of my friends train him (the facility's medical director)."

FRINGE BENEFITS

The pacemaker industry is notorious for its generosity to physicians. Here are some examples:

—One company rented the *Queen Mary,* a complete Las Vegas show, and other big name entertainment for pacemaker physicians attending a convention.

—The next year, a competitor, under similar circumstances, hired Doc Severinsen to play at a reception.

—A third company hired George Burns to host two sitdown dinners for the firm at a convention earlier this year.

—Not to be outdone, a fourth hired the Dallas Cheerleaders to host a similar reception.

TRAVEL

Very commonly, pacemaker firms arrange to fly doctors and sales representatives around the country under one pretext or another. The most frequent offender, according to most sources, is Intermedics of Freeport, Tex. According to several sources, Intermedics has a fleet of jets, helicopters, and a 55-foot Hatteras yacht that exists for the primary purpose of encouraging physicians to come "visit the plant."

In a typical situation, the physician is asked if he had ever seen a pacemaker made or, alternatively, if he would like to go fishing. If interest was expressed in either alternative, the company arranged transport on company planes to the plant. After a quick

tour of the plant on Friday afternoon, the physician is invited to spend the weekend cruising the Gulf of Mexico on the company yacht.

The trip is said to be in such demand that a quota has been established parceling out sailing time to the various sales regions. Alternatively, if the physician is not a sailor, the suggestion is made that he might enjoy the use of the firm's hunting lodge.

Other pacemaker firms have also participated in this activity. Some of the examples found by the committee include:

—Ski trips to Vail and Europe.
—Vacations in the Caribbean.
—Trips to Australia.
—Las Vegas gambling junkets.
—Salmon fishing in Alaska.

GIFTS

Pacemaker firms' generosity extends to gifts of all kinds. Here are some examples:

—One firm allegedly gave gold-plated shotguns to cardiologists in Georgia.
—Another firm routinely gives tickets (including flight and accommodations) to the Indianapolis 500. The pretext for the gathering is a "training session" timed to coincide with the event.
—Leased luxury cars given to cooperating physicians.

WARRANTIES

The structure of most pacemaker warranty provisions includes the payment of expenses beyond those covered by medicare and other third-party payers. The frank admission of most salesmen is that this policy is intended to "fully compensate" physicians for the replacement procedure. In at least some cases, this policy has been interpreted by physicians as an invitation to "write your own rebate," as a specific inducement to do business, and an attempt to purchase product allegiance.

The following statement is an example of this policy:

Physician: "The next thing I have to ask, which is, warranty. In the event of failure of the pacemaker, assuming a credit toward the purchase of——"

Salesman 4: "Not toward anything, it's an exchange. Let's say you put in a VVI pacemaker that failed, then another VVI for no charge. If you decide to exchange, after this pacemaker failed, to put in another pacemaker which costs more money, they would pay the difference. Say it was a $200 difference. Now, that credit can either go to you personally or to the patient. We don't make a judgment as to where it's going."

A second example was obtained in California: "We pride ourselves on followup," the salesman said. "With our no-hassle warranty, if you replace a competitor's product with ours, we give a $450 credit toward associated hospitalization costs. The $450 says you have agreed to use our company from here on out. It's good business."

BUSINESS EQUIPMENT

By far and away, the most common inducement offered, involved the "gift" of ancillary devices associated with pacemakers. These devices include:

Programers.—Programers are used to set the operating parameters of a pacemaker with a variable rate. Programers that cost $700 to $900 to manufacture, retail at around $2,000 to $3,000.

Analyzers.—Analyzers are used in the operating room to determine if the electrode has been correctly placed and the level of stimulation necessary to pace the heart achieved. Analyzers cost around $1,000 to manufacture and retail for $2,000 to $3,500.

Transtelephonic transmitters.—Telephonic transmitters are used in the followup process to monitor the performance of the pacemaker. Basically, a single lead EKG is transmitted over the phone to a receiver in the pacemaker center or in the doctor's office. Transmitters cost $50 to $70 to make. They are sold for $200 to $250.

Receivers.—Receivers accept telephone transmissions, decode the signals, and print the EKG. They cost about $1,000 to $1,500 to make and retail for $2,500 to $3,000.

Miniclinics.—Several firms manufacture and make available "miniclinics." These devices are essentially small, portable units designed to monitor the performance characteristics of the pacemaker. Their manufacturing costs average about $150. They are sold for $300 to $400.

In most cases, the equipment detailed above is essential to the operation and follow up of the pacemaker. Questions of concern arise, however, when this equipment is dispensed without need, escalating, thereby, the total cost of the procedure to the taxpayer, or offered as an inducement to do business.

The legitimacy of both concerns was repeatedly documented in our investigation. The proliferation of these devices and their cavalier dispensation is inescapable. Since the various devices manufactured are incompatible, it is not uncommon for a hospital doing pacemaker implants to have two sets of each of the devices detailed above for each manufacturer. The result is that many hospitals have 20 to 30 of these ancillary devices permanently stocked and awaiting use. The associated program costs covered by this wasteful activity are incalculable but clearly significant.

The waste associated with the misuse of ancillary pacemaker devices is augmented and of greater concern when the gratuitous availability of these devices is predicated on "doing business." The following illustrative statements are drawn from our committee's activities in California and New York:

Salesman 4: "Let me tell you a little bit about what we can work for you. All of our equipment is offered totally free of charge. We wouldn't charge you for any of the transmitters. We won't charge you for the machine (receiver). We won't charge you for the paperwork or to train someone how to set up the clinic itself, because obviously this doctor is not going to sit and play with the telephone all day long. * * * So there is absolutely nothing in terms in money out to you. What we want, what we would like is if the doctor likes our pacemaker, we want him to refer our name, or to use our pacemaker as much as possible."

"All our equipment is offered totally free of charge. We wouldn't charge you for any transmitters. We wouldn't charge you for the receiver. We wouldn't charge you for the paperwork or to set up the clinic."

Interview With Salesman 3

Staff: "So what you're saying is that really all we have to worry about in terms of cost, initially, is what we spend for the pacemaker?"

Salesman: "Everything else would be support."

Staff: "That includes this pacemaker monitor, and the programer——"

Salesman: "Programer, the monitor, followup equipment, generally what we do. Each pacemaker that you implant you would get one of these for the patient at no charge and the receiver. I don't know offhand, depending on numbers, I can get you a receiver."

Staff: "What does that receiver cost?"

Salesman: "We have a new receiver. It is a bit more complex than the standard ones. It lists for about $3,100."

Interview With Salesman 2

Salesman: "Well, generally, the doctors work two ways; either they are using one or two brands of pacemakers, one or two models, they have the programer there, if they are comfortable with using them, or if when they want to change something they call the factory rep. We come and we bring it."

Staff: "So, if we needed one you would come out?"

Salesman: "Yeah, it's not something you buy. If you want it we give it to you. I give it to people if I feel comfortable with them using it. There are some doctors that I've given them to, then I've taken them back because they screw things up."

Staff: "They don't know how to do it?"

Salesman: "Or they don't really know what to do."

Interview With Salesman 4

Salesman: "You can have five receivers if you need them. If you want a receiver for your own private office, you can have five of them, as many as you actually need. We don't want the receivers to be obviously laying in your file drawer."

Cooperating Physician: "No, that doesn't do anybody any good."

Salesman: "But if you need five for five different offices, for five different people who are monitoring you can have five of them. And of course the transmitters."

Physician: "The patient transmitter?"

Salesman: "Comes free of charge. The magnet (another device used to monitor pacemaker performance)——"

Physician: "OK. That's one per patient. Is that right?"

Salesman: "We'll give you dozens. We'll send dozens."

Excerpt From Interview With Salesman 7

Salesman: "Programers, those are no charge. Receiver, I can get to you and I'll pay for that. The analyzer I got, I'll come in on every implant. You know four implants a month, that's no problem because I'm always around here anyway. Transmitters come with each pacemaker. They are free of charge."

Interview With Salesman 17

Salesman: "Programers we provide free of charge. If you need one, two, or three we provide those for you."

Salesman 4 provided this summary.

Physician: "Do you have a basic systems analyzer?"

Salesman: "Oh sure."

Physician: "Can we get that?"

Salesman: "Well, it costs $3,500. You can get it if we are doing business with you. You get one, no problem. So what we can offer you is, No. 1, service, whenever you need us, you will get it. If you call me up and say, I need 25 of these, I'm not going to say to you, OK. I'm going to call up and we'll get them. I will bring them over to you. If you say to me, my nurse, who's monitoring, can't come tonight and I have 50 patients who are calling up in 3 hours, I will come do this for you. If you need us in the O.R., we will be there. Arrangements can be made if financial matters are pressing to you in any way, totally free of charge (phone is ringing). And as I told you the equipment comes free."

E. Overutilization

In the United States, the use of pacemakers is more than twice that of the next highest user in the free world and five times the average. Applications for pacemaker therapy have been significantly expanded in recent years—with the active encouragement of the pacemaker industry—to include a variety of ambiguous conditions where the prescription of pacemaker therapy is of questionable value.

The United States implants more pacemakers per capita than any other country in the world. In 1975, there were about 270 new pacemaker patients per million population in the United States, nearly one-third more than any other country.[5] By 1978, the rate of implantation in the United States had reached 310 per million. The current level of implantation is estimated at over 500 per million compared to a free world average less than one-fifth of that total.

The use of pacemakers in the United States and its rate of growth has traditionally been attributed to the development of new applications for proven technology and the general aging of our country. Increasingly, however, critics charge pacemakers are overutilized and unnecessarily prescribed.

The main use and greatest success of the pacemaker has been in the treatment of Stokes Adams' syndrome and heart block. Before the development of pacemakers, half the patients with Stokes Adams' syndrome died within a year of diagnosis. Presently, with a pacemaker, the expectation of life of these people is practically the same as for people the same age without the disease.

Increasingly, with the active encouragement of the pacemaker industry, applications for pacemakers have been extended to sick sinus syndrome, preheart block, atrial disease, tachyarrhythmias, and congestive heart failure due to arrhythmias. Prescription of

[5] PACE. vol. III, January-February 1980, page 2.

pacemakers for these conditions is a "judgment call," justified more often than not as an insurance against the development of heart block or simply to improve the quality of life for the patient.

The ambiguity of these secondary diagnoses and the difficulty of assessing success have led some physicians to question the appropriateness of the therapy. At least one critic, Dr. Thomas Preston, University of Washington School of Medicine, believes the use of pacemakers for preheart block and sick sinus syndrome was stimulated by the pacemaker manufacturers.

In the March-April 1981 issue of PACE, Dr. Preston indicated:

> Prevailing attitudes about utilization are due in no small part to blandishments by manufacturers to pace all patients with these syndromes. Marketing strategies, beginning in the early 1970's, aimed at widening the pacemaker market through "education" of physicians by direct exhortation by the sales force, support of symposia and speakers favorable to expanded indications for pacing, and commercially generated literature. In 1975, a leading manufacturer advised physicians, through a "scientific exhibit" at professional meetings, that all patients with bifascicular block or "sick sinus syndrome" should get pacemakers. Thus, medical indications were influenced and generated not entirely by scientific information about biological needs of patients.[6]

Dr. Preston concluded blanket statements about the efficacy of pacing are not justified by current information.

> We have no good data to support the practice of prophylactic pacing.

A number of other authorities have expressed similar concerns:

—In a study supported in part by a National Heart, Lung, and Blood Institute grant, Dr. John McAnulty concluded in 1978, that routine prophylactic use of permanent pacemakers was inappropriate.

—A 2-year study at the Brooklyn Hospital in New York, keyed to the implementation of a retrospective peer review, found a significant incidence of what appeared to be inappropriate utilization. The review indicated that as many as 40 percent of those who had received a pacemaker prior to the peer review were to receive medication that would have produced the condition for which the pacemaker was prescribed. An additional 10 percent of the patients who had received pacemakers before peer review were found to have other conditions that might have accounted for the events that precipitated the decision to implant a pacemaker. In the 2 years following the imposition of peer review in the hospital, initial implants declined by 54 percent. There was no change in the number who receive pacemakers for advanced or complete heart block.

—Over a 3-year period, 32 patients who had received pacemakers were referred to the Peter Bent Brigham Hospital, Harvard School of Public Health. After a comprehensive clinical evalua-

[6] PACE, vol. IV, March-April 1981, page 285.

tion undertaken to assess the need for pacing, the judgment was made and the pacemakers previously implanted were removed as unnecessary. The study concluded that the cost of lifetime pacemaker management exceeds $17,000 per patient, money which could be saved with improved selection of patients for pacemaker implantation.

—In April 1982, at a meeting of the North American Society for Pacing and Electrophysiology, physicians from the Boston University Medical School presented a paper indicating at least 24 percent of the 59 pacemakers implanted in 1980, at a community hospital in Boston, were unnecessary. The implantation of an additional 17 percent was questioned.

—In July 1982, the Public Citizen's Health Research Group released a study, concluding at least one-quarter of the pacemaker operations conducted in Maryland during 1979 and 1980 were not necessary. An additional 12 to 14 percent were considered questionable. The research group estimated the cost of the unnecessary operations in Maryland at about $2.8 million a year.

The difficulty of assessing the appropriate utilization of pacemakers is demonstrated by a study performed by Dr. Michael Bilitch, University of Southern California, in 1982. Twelve case summaries requiring judgment on whether or not to implant a pacemaker were presented at a meeting of the American College of Cardiology. Consensus of the need to implant a pacemaker was achieved in only 2 of the 12 cases.

F. Monitoring

Medicare's frequency guidelines for pacemaker monitoring and payment levels appear excessive. Payment for transtelephonic monitoring appears outrageous, particularly since manufacturers supply all the essential equipment.

After implantation, the performance of the pacemaker and its impact on the patient are followed in some combination of the following three ways—physician's office visits, pacemaker clinic visits, and telephonic monitoring. These methods are employed either alone or in combination, depending on physician preference and patient's condition. Physician visits for this purpose generally range from a minimum of 1 a year to a maximum of four times a year. Pacemaker clinic visits are generally scheduled on a quarterly basis. Transtelephonic monitoring has emerged as the most widely employed followup mechanism.

For purposes of transtelephonic monitoring, the patient is provided with a telephone transmitting device. The device transmits either a single lead electrocardiogram (ECG transmitter) or a "spike-pulse" transmitter which measures the interface of the pacemaker's firing with the patient's pulse.

Either system provides the receiving physician with a rhythm strip which serves to measure the spontaneous heart activity and the performance of the pacemaker.

Pacemaker followup services are covered by medicare. Charges for physician visits and pacemaker clinic visits vary with prevail-

"If you use us, I'll provide you with a transmitter."

ing rates and customary charges. Transtelephonic monitoring rates vary as well within a set frequency schedule.

In 1979, the existing frequency schedules for telephonic monitoring were reviewed by a select committee at the National Institutes of Health. The purpose of the meeting was to provide HCFA with advice regarding appropriate schedules for telephonic-cardiac pacemaker monitoring.

At HCFA's request, the National Institutes of Health convened a select committee of experts who provided guidance in updating the frequency schedules in light of the development of lithium powered pacemakers and other developments. Among those participating in the meeting were the inventor of the implantable cardiac pacemaker, designer of the lithium battery, developer of the transvenous implant approach, cofounder of the first hospital based transtelephonic monitoring system, representatives of regulatory agencies, and commercial monitoring concerns.

The consensus of the group was that the exiting frequency schedules geared to mercury-zinc units, was outmoded and inappropriate for lithium powered units. The panel recommended the continuance of the existing schedule for those mercury-zinc units remaining in service and the development of a second schedule for the more reliable, long-lived lithium models.

The mercury-zinc schedule allowed "appropriately spaced transmissions once every 2 months during the first 6 months following implantation; once each month during months 7 to 15; once every 2 weeks during months 16 to 18; and once each week after the 18th month for the life of the pacemaker." The schedule was designed to allow for increased monitoring as the device approached its projected "end of life."

The panel considered schedules for lithium units that would differentiate between types of patients (i.e., high risk and low risk), but rejected the approach on the argument that patient's dependency status is too difficult to define and out of concern that a service-specific approach would be hard for the intermediaries to handle.

There was also strong disagreement as to whether the frequency schedule should be established as monthly or every 2 months, with the exception of more frequent monitoring during the first weeks after implantation (the period when most lead displacements occur). Ultimately, the recommendation was made that a monthly schedule be established as the level of care that would be paid for automatically. Beyond that point, documentation of medical necessary would be required for the individual patients. The panel concluded with a strong recommendation that the group be reconvened at least annually to review the monitoring schedule established, given the complexity of, and the rapid development of, cardiac pacemaker technology.

Despite the panel's recommendation, there is no evidence the frequency schedule has been reviewed since it was established in 1979. There is strong evidence that medicare's minimum monthly schedule and related payment for that service is inappropriate.

By every account, frequency schedules and payment levels for transtelephonic monitoring are excessive. Monitoring is viewed as a lucrative activity requiring limited time and no capital expense

for the physicians and clinics following pacemaker patients. Most of the necessary equipment, plus the technical guidance necessary to establish the service are "donated" at medicare expense.

In our interviews, we found most pacemaker salemen intimately aware of the medicare monitoring frequency and payment levels. Every salesman we saw but one offered to set up a monitoring program and provide the necessary equipment if we did business with his firm. About one-half indicated their services included providing specific medicare payment and billing information.

The extracts below, taken from some of the interviews with New York sales representatives are typical:

Salesman 1: "What we have then is a system for following patients. You can have 10 to 15 or more on telephone monitoring, once a month, 12 times a year, every year the pacemaker is in, and some last 10 years. And they now allow 80 percent of $45. You're talking about $38. All you have to do is have a technician who knows how to take an electrocardiogram over the phone, and then all it takes is a 15-second read.

"If you have 30, 40, 50 patients with pacemakers, you can have a technician or whoever take them in 2 hours. And there you're talking about a cost of practically zero. And for zero cost you're getting $38 each time.

"Most of the doctors I work with do it. Get $800 for surgery, that's 20 minutes and $380 a minute for following. A lot of them do $50,000 to $100,000 just for scanning EKG's. It costs a 6-inch strip of EKG tape and electricity."

Salesman 2: "It's a lucrative business, followup on pacemakers. Medicare reimburses from 80 percent of $28 to $60, depending on a number of factors I can't figure out. The lowest reimbursement that I've ever seen was 80 percent of $28, and it takes a secretary over the telephone about 3 minutes."

Sales representative No. 4 arrived with the medicare frequency guidelines, payment levels, and billing codes. She said the transmitter provides basically an EKG that indicates pulse rate and interval.

Staff: "Why do you need these things?"

Salesman: "Basically, it's because medicare is not going to reimburse you unless you have that."

Staff: "Why is that?"

Salesman: "Part of the documentation that they require."

Staff: "They just want to know that, so you got to tell them?"

Salesman: "Exactly. Do you know what they, you know how much money that they get? It's unbelievable. The first time you monitor a patient, this has to be an office visit. Let's say a Dr. ————, a cardiologist would have to be there for that first time. The first followup is at $119.75—$119.75, can you believe it? That's only for the first."

Staff: "The first?"

Salesman: "Right, so one-shot deal the first time. But other—we'll get to the rest of them in a minute. $119.75 is the first time you come to the office. Doctor looks at the incision. Is it clean? Has to describe it, listens to the heart and lungs. Do they sound clear, or not? Describe it. Take a rhythm strip. Note the rate or interval. Get the code number, 9820, and $119.75."

Staff: "The whole thing takes, for example——"

Salesman: "Five minutes. Not even 5 minutes. If the medication is changed, there is a different code number, 9821, and $140.68 is what you get back. Of course you can bill $200, but this is the maximum—$146.80. It's unbelievable. You can make one-quarter of a million dollars doing this, after let's say 3 years of building up patients."

Staff: "How many patients?"

Salesman: "I know a group here in Brooklyn, they have 400 pacemaker patients, 400 that they are following. They take in well over one-quarter of a million dollars."

Staff: "That is a lot of money."

Salesman: "And this is legal. Here it is from medicare itself. I happen to have found out what the reimbursement rates are, but here are all the codes and frequency guidelines. This from medicare. I didn't make it up. So this is basically how I got into seeing a lot of doctors that didn't want to use, that didn't care about————(company name). We set up pacemaker clinics with them."

Staff: "It sounds like an easy thing to do."

Salesman: "Very easy."

Staff: "I'll have to have somebody there to take care of this for me. What kind of a person do I need? Do they have to be a technician of some kind, or can I train a nurse?"

Salesman: "You can train a nurse very easily. The best bet would be a nurse after hours, someone who works there from 7 to 3, to come in for a couple hours afterwards."

Staff: "That's all it takes?"

Salesman: "That's all you would need. Because if you get organized, which I could help them with before anybody sets a desk to do this. If you get organized that's all you need. Every patient has a time, specific time when they call in. You either mail them postcards or you tell them on the phone, I want you to call at 5:05 next time. They're pretty good about it. Or you could call them But it's better for them to call you because otherwise you are paying for the phone calls."

Staff: "Is there any rule of thumb? How many are we talking about, an hour, say?"

Salesman: "You can do 16 an hour very easily. You could have a nurse do it, or you could have a medical technician do it, or you could have someone who doesn't have that much training but is bright. * * * You're not paying anything" the rep concluded. "I mean stamps. You have to pay stamps right? Because you are sending it in the mail. That's basically it."

The impact of this approach on the quality of service was expressed by another salesman. "Generally, some of the cardiologists and some of the surgeons, like to do followup because they make money on it," he said. "And in some cases they feel it keeps them closer to their patients, but generally, it's the money. If you're billing medicare, one group of doctors I know has one nurse working part time following 700 patients. And the job she does is grossly inadequate. I've seen her working and I get upset. I get upset when I see people who should be doing a good job, doing a bad job, and missing things, or not even looking for what they should be looking

for. I got upset with her one day because she took something over a telephone transmission which was garbage. She said that's fine, talk to you next month, and hung up. Wait, this is not right. She said don't bother me."

The concerned salesman suggested monitoring 16 patients per hour was excessive. "Doing the job right, one person can monitor 12 patients an hour," he said, after 3 months of following people. "That includes writing up the medicare forms."

G. Warranties

Medicare lacks a systematic process for tracking pacemakers replaced within warranty periods and assuring warranty credits are used to offset future medicare costs necessitated by the replacement. More often than not, warranties offered by the pacemaker manufacturers are deceptive, dishonored, and inappropriately limited to subordinate the manufacturers' liability to medicare.

In concept, the warranty of a pacemaker is a guarantee to the user (physician and patient) that restitution will be made for defects in workmanship or quality should the pacemaker not operate properly and fail prematurely. The time limit of the warranty is selected by the manufacturer, based upon knowledge of past pacemaker performance, engineering estimates of future performance, and financial feasibility.

In practice, pacemaker warranties are a sham, a marketing gimmick, at best, and at least in some cases, camoflauge for kickbacks and rebates. In general, pacemaker warranties are more honored in the breach than in the observance. The practices detailed below limit the applicability of pacemaker warranties:

The manufacturer.—A warranty is only as strong as the firm offering the warranty. Most pacemaker companies currently offer either a 10-year or "lifetime" warranty. Since the average life expectancy of a pacemaker patient at the time of implant is around 7 years, even the most modest of these warranties is 3 years beyond. It is also considerably beyond the life expectancy of many pacemaker firms.

In the last 6 years, seven manufacturers have dropped out of the U.S. market. Of the 10 remaining manufacturers who marketed pacemakers in the United States since 1976, two are said to be marginal, and one, American Pacemaker, is in the process being subsumed by another (appendix O).

Trading up.—Most industries faced with significant recalls would anticipate s substantial impact on sales and income. In the peculiar economics of the pacemaker industry, a product failure offers an opportunity—the incentive to "trade up."

Between 1976 and 1977, for example, Medtronic had to recall over 35,000 pacemakers that allowed moisture to seep inside and disable the units' batteries. At the same time, Medtronic's competitors were unveiling "state of the art" lithium battery pacemakers not similiarly subject to failure. given the replacement cost of about $400 for each of the 35,000 units and the competitive factor, an analyst might expect Medtronic to show a loss. In fact, by the end of fiscal year 1978, Medtronic's sales volume actually increased 23 percent over the previous year even though its unit sales stayed

flat. The serendipity was the result of the difference in cost between the recalled model (Xytron with a sales cost of $1,400) and the then top of the line Xyrel (cost $2,295).

According to a former corporate officer of Intermedics, a similar concept led Intermedics to purchase the failing Arco line in 1980 and make a purchase offer to American Pacemaker in 1982. In August 1981, Intermedics sent a registered letter to physicians who had implanted the three Arco models informing the physicians that the pacemakers had been exhibiting premature battery depletion without adequate end-of-life indications. The firm recommended that all referenced Arco pulse generators should be prophylactically replaced, at the discretion of the physician, by the 34th month after implant, if explant is not contraindicated by the medical condition of the patient (appendix P).

Intermedics informed the physician the firm would honor Arco's reimbursement policies and "expanded options available for replacing the specified models." Effectively, what this action accomplished was to offer Arco physicians the uncomfortable choice of leaving a potentially defective unit in their patient, at the hazard of the patient's health and potential resultant litigation, or replacing the unit with an Intermedics pacemaker and being locked into dealing with that firm. Replacement costs associated with any other manufacturer's device would not have been honored.

All pacemaker manufacturers currently offer a replacement credit. The credit ranges from a purchase price credit (applied to the purchase of another unit—generally of higher price) to full credit replacement (device for device). In addition, most firms offer the additional replacement incentive of covering all or some portion of the "uninsured medical expenses."

WARRANTY EXAMPLES

The following examples express the range of warranties offered to the committee in California and New York. They also illustrate the use of pacemaker warranties as an inducement to do business.

Salesman 14: "Warranty? We will stand behind the pacemaker. If Mrs. Jones has a pacemaker and it's supposed to be in for 8 years, and at the end of 3 years it's not functioning right for her, and the doctor says this would be more beneficial for her heart, we reimburse Mrs. Jones the amount paid for the original pacemaker and only charge for the difference between what we're now getting and what we paid before. If she doesn't have insurance we will pay up to $5,000 of unreimbursed expenses. * * * Where this is important is with the doctor. He hates to sit there and wait for medicare and medi-cal to reimburse him. He knows he's going to get paid. So he's a lot of the time more cooperative. It's called our pacer exchange program. It's dropping something out to lure business in. We will pay up to $1,000 reimbursement if someone comes in with a pacer that's not functioning or needs to be replaced for some reason and it's not ours. We will pay up to $1,000 of the unreimbursed expenses for the individual. You'll find that does not exist in other places. It's something I'm proud of."

Salesman 17: "We have an excellent warranty. The warranty states that we—and this would be good costwise—if the pacemaker

fails for any reason, we will reimburse you or your patient up to $5,000 for uninsured medical expenses. Anything that's not covered by any kind of medical insurance. It also states that whenever this device wears out the patient will receive a pacemaker at no charge."

Staff: "How does it work?"

Salesman 17: "When you have your bills and figured out what medicare pays, and the others, send us the total at the bottom and we will pay you whatever's left."

Staff: "Do you pay the hospital or the patient?"

Salesman 17: "Basically it's supposed to go to the patient, but we have had situations where, for whatever reason, it's gone to the M.D.'s. It depends on the working relation we have with the organization or the M.D."

Staff: "What about the patients we have with other manufacturer's devices. Is there a crossover warranty?"

Salesman 17: "Most cases, what most companies do, say to replace our device with Medtronic, you would get nothing. We have a freedom of choice program. It says, basically, that we will provide a $500 credit toward the purchase of our pacemaker upon the replacement of an existing competitive unit. That's a big factor when cost is concerned."

Salesman 3: "Let's start with warranties. On all our pacemakers and electrodes it's a full lifetime warranty. What that means is if the pacemaker fails for any reason, battery depletion, during that patient's lifetime, the pacer will be replaced with a pacemaker of equivalent cost. If they happen to be more expensive, then they have to make up the difference. They'll also reimburse up to $500 of uninsured medical expenses."

Staff: "So what you're talking about is what credit of some kind would have to be replaced. The value credit—is that what it amounts to?"

Salesman: "Yeah."

Staff: "Then the uninsured medical costs——"

Salesman 3: "If the pacemaker is a $3,000 pacemaker, and for any reason it fails during a patient's lifetime, they'll be credited $3,000 toward the cost of another pacemaker—understanding that the changes are the cost of pacemakers that year are going to be up. But then there's always a cheaper version."

Salesman 14: "Warranty? Absolutely best in the industry. I picked up a lot of business because of the warranty we offer. We give full credit toward another pacemaker and up to $5,000 for hospitalization/doctors expenses not covered by insurance."

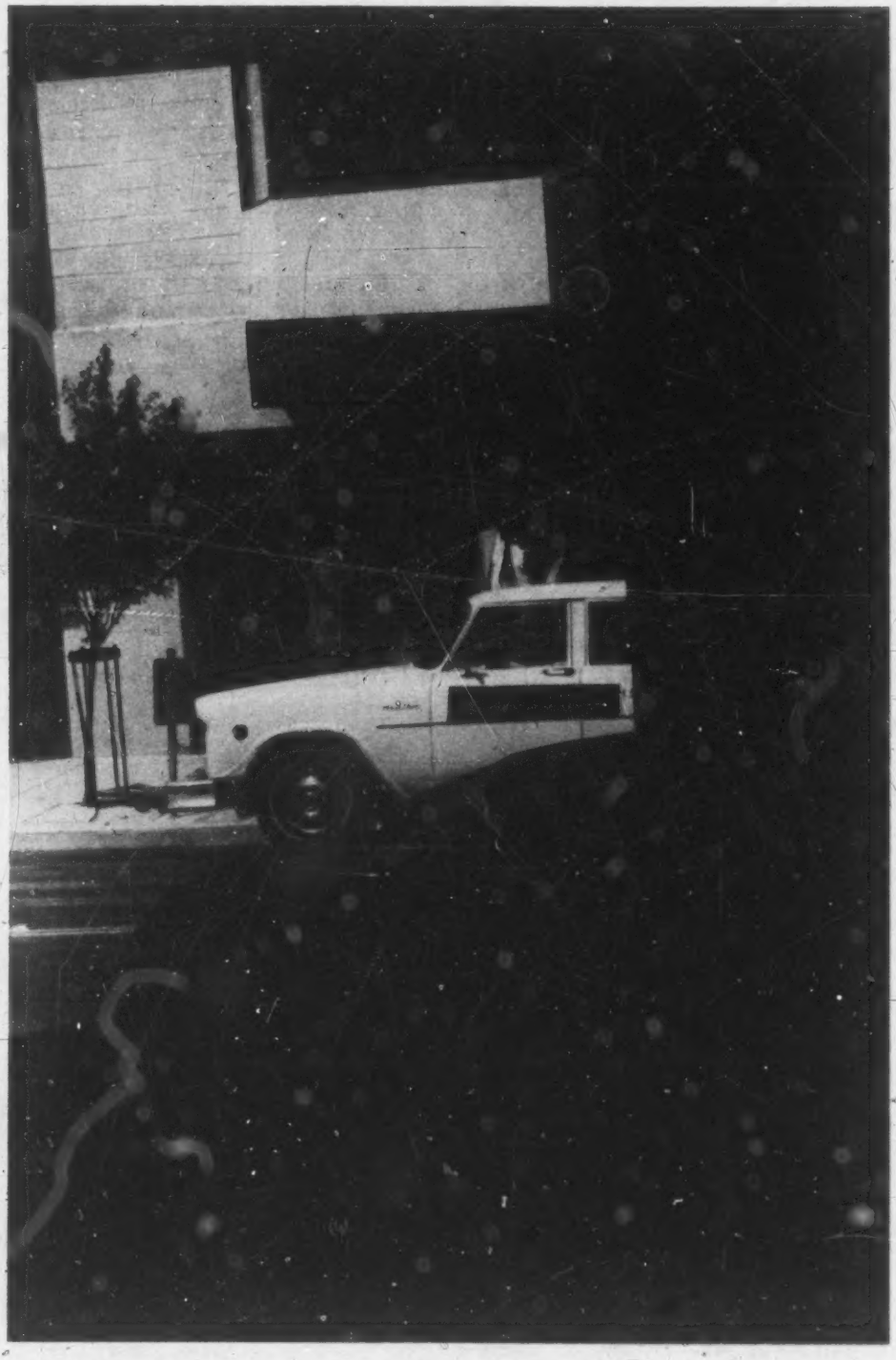
Salesman 18: "We will pick up all uninsured medical costs at that time. This is true in all replacements. If the device is still in warranty, we will replace the unit. If it's outside warranty, just uninsured medical costs."

Salesman 12: "We offer a 'lifetime warranty.' That's really, really important. With our 'no-hassle warranty,' if a physician makes a decision to replace the device we give full credit or if you prefer, pick up the extra costs. We pioneered that system. No one else has it. We make sure the patient is No. 1 by taking the hassle out of replacement."

Staff: "What if we go from other companies to you?"

Salesman 12: "We will pick up at least $500 for explant of third party. Even if you buy our cheapest model ($2,000.95). We will still pay $500 toward medical expenses."

"Even if you buy our cheapest model, we will still pay $500 toward medical expenses."



UNINSURED MEDICAL EXPENSES

Uninsured medical expenses are defined as costs beyond those accepted by medicare and other third-party payers. In practice, medicare will pay all but about $400 of the replacement cost (regardless of warranty). The average is the difference between cost and charges and generally reflects that portion of the physician's fee that would be passed on to the patient. Effectively, by guaranteeing these costs, the manufacturers provide a powerful incentive for physicians to replace pacemakers.

The impact of this policy is demonstrated by the following example. In December 1978, Medtronic, faced with massive failure of its Xytron models informed physicians:

> Should you conclude at any time that the patient's medical interest is best served by replacing the Xytron with any other Medtronic pulse generator, we will pay the patient up to $450 of uninsured medical expenses incurred in the replacement procedure.

In January 1979, the firm published an addendum extending its offer to the entire Xytron product line, eliminated language conditioning the credit on product specification performance criteria and offered an additional $100 credit to any hospital replacing the Xytron unit with a programable Xyrel.

The financial analyst group, known as F. Eberstadt & Co., provided the following analysis of Medtronic's action:

> Basically Medtronic is giving tacit approval and an economic incentive to replace all Xytrons. We expect virtually all Xytron pacemakers still implanted in the United States to be removed within 12 months.
>
> In our opinion, Medtronic's reason for instituting the Xytron patient management option, despite the fact that the performance of wave-soldered models is quite satisfactory, are as follows: (i) Medtronic would like to encourage the replacement of Xytrons functioning normally in order to minimize the number of "no-output" sudden failures, each one of which reminds the physician of the entire Xytron affair; (ii) because Medtronic is requiring that an explanted Xytron be replaced with a Medtronic pacer in order for the patient to qualify for the $450 payment, physicians may be discouraged from switching to another manufacturer; thus, Medtronic's market share may benefit; (iii) since the incremental gross profit on a Mirel pacer probably exceeds $1,500, $450 is a reasonable cost to incur for an incremental unit sale.

A small indicator of the direct impact of this policy is provided by FDA main district office memo dated February 14, 1979. The memo states the FDA had been informed one Pennsylvania physician replaced 67 Xytrons in 1 week—the week of January 15, 1979. The line between a warranty that includes "uninsured medical cost" and a rebate or kickback can be difficult to define. At best, when paid directly to the patient, if offers the beneficiary the comfort of knowing they are insured in the event of product failure. At

worst, the policy, particularly when paid directly to the physician, is incentive to operate and "write your own rebate."

WARRANTY COLLECTION

To the extent that warranty replacements or credits are offered, there is evidence it is rarely invoked and the credit returned to medicare. Replaced generators are frequently discarded and not returned to the manufacturer. Without a centralized record of pacemaker patients and a mandatory failure reporting mechanism, tracking is difficult, if not impossible. Even when returned to the manufacturer, performance of the devices and, therefore, validity of warranty is exclusively determined by the manufacturer. Earlier in the year, the Department of Health and Human Services released an audit of a Denver hospital confirming the problem. The removal of four warrantied pacemakers was identified. In all four cases, the devices were returned to the manufacturer. The Inspector General, Department of Health and Human Services found the warranty was not honored in any of the four cases.

In effect, medicare and the taxpayer are, to a considerable extent, assuming the manufacturer's responsibility for insuring the safety and effective operation of pacemakers. Too frequently, medicare, as in the Madeline Garman case that initiated the committee's inquiry, winds up paying all or most of the replacement costs.

The monetary impact of this policy is illustrated by the following example: When the Arco lithium chemistry was found to be problematic, it triggered the removal of all suspect Arco pacemakers. One physician told the committee he removed 36 of the units. The cost to the hospital, and ultimately medicare, was said to be one-half million dollars.

The Medical Device Amendments of 1976 includes a provision whereby manufacturers and others who introduce a device into interstate commerce can be required to repair or replace a device, or refund the purchase price if it is found to be improperly designed and/or manufactured. There is no evidence this provision has ever been invoked by the FDA in any of the 30 pacemaker recalls noted.

H. The Role of the Pacemaker Salesman

The critical element in the pacemaker industry is physician/salesman relationship. In order to encourage the use of the device they sell, pacemaker representatives train or arrange for training of physicians in pacemaker procedures, participate in pacemaker implants, provide guidance in operative procedures and device operation, provide "free of charge" as an inducement to do business necessary ancillary equipment, and counsel in billing procedures to maximize reimbursement from medicare.

Since pacemaker surgery is not a speciality in itself, too many surgeons depend on sales representatives for training, guidance, and technical assistance. This dependence of the physician on the pacemaker salesman, the absence of qualitative difference between the devices, and medicare's open-ended funding have combined to establish the pacemaker salesman as the single most important element in the pacemaker industry.

The most successful method to gain market penetration has been to pirate the competitor's sales force. Hundreds of lawsuits have been filed by pacemaker firms warring for the services of particular sales representatives. Bidding for sales representatives rivals baseball's free agent free-for-all. Salaries range from around $50,000 a year to several million dollars a year.

The services the pacemaker salesman performs for this reward are best described by the salesmen.

Salesman 1: "The (pacemaker) salesman will do anything for you. Any salesman will. Face it, prices aren't that different. We're a little cheaper on most models, but just a few hundred dollars. What it comes down to is service. We do anything you can think of. And if you can think of it, and we aren't doing it, we'll start."

"I think of myself as a technician—not a salesman. I go into the operating room and do whatever needs to be done to help. When something goes wrong the doctors don't want to hear possibilities. They want an answer."

SALESMEN IN THE OPERATING ROOM

Salesman 14: "My function as a salesman is to attend all implants and take thresholds as the place for the lead. I also work the PSA analyzer. It's a good way to stay in touch."

Salesman 17: "We make ourselves available on a 24-hour basis—not only for phone calls but for surgical procedures. And that's what we do. I mean I spend a good part of my time attending cases in operating rooms. Not doing any implants. But advising and giving my best educated guesstimate as to what's going on, or how to bail an M.D. out of a situation where he might say the lead is fractured, or it looks like it is fractured and how can we find it. And if it is, what are the alternatives. Is it to replace the pacemaker or the wire or what?"

Staff: "Well did you go to medical school then or what?"

Salesman 17: "No, I just have about 10 years of sales experience in the health field. I've been with this firm only since March. I've started my own business in which I deal only with this company. But prior to that, all my experience was in sales and prior to that as a manager for Medtronics in California."

Staff: "It sounds like you've been through a number of these situations."

Salesman 17: "Without exaggerating, I've been through literally hundreds of cases. For the last 10 years, virtually one to two every single week—a minimum of one or two every single week and sometimes two or three. When I was in New York, working in the Bronx and Westchester County, it was two or three every day. It's fun."

Staff: "Let me ask you about the surgery. You aroused my curiosity. I'm surprised to hear you were going to one of the implantations. Is that fairly common? What are you doing there?"

Salesman 14: "What we do in there—we give them the introducer stick. I watch the EKG monitor. What I'm looking for is a premature beat caused by the electrode touching the heart wall. The doctor's looking for a good run—an active area of the heart. They

hook a lead to the analyzer. I have to test the connection. It may be done in 15 minutes and it may take 6 hours."

Salesman 3: "The other thing to consider is starting these implants if there is no one trained in doing implants. I can go into the operating room. I do all the measurements and help support the doctor. I've done—7 years I worked at the hospital. I've done around 1,000 implants. Pretty much any problem that can occur I've seen during the implant. I can trouble-shoot."

Staff: "So you actually go into the operating room with them and look at a problem and you can help them."

Salesman 3: "I don't at Montefiore. Furman has his own staff and he doesn't want me in."

Staff: "He doesn't need any help?"

Salesman 3: "He doesn't need any help. Generally at the smaller hospitals, what I'll do is I'll scrub up and I'll go in and do all the emissions. I have another device that tests thresholds and tests the pacemaker. I also kind of coax them along in placing the leads. If they get hung up on a valve or something I can help them along."

Staff: "You go in the operating room and test leads and that kind of thing, and just try to see they are working right?"

Salesman 4: "Right, exactly. Just to make sure that that lead is in the proper location."

Staff: "So what you're really doing is making sure that you make the right kind of connection?"

Salesman 4: "Exactly."

Staff: "How can you tell?"

Salesman 4: "We have a little computer, it's called an analyzer. It's a very sophisticated temporary pacemaker. And we analyze the voltage, the amount of voltage needed to stimulate the heart."

Staff: "Can the doctor do that?"

Salesman 4: "If he wants to he can do it. But we'll do that free. Because I'm sure he's very well aware of what goes on. You go in there and the anesthesiologist is, like, on drugs. It's true isn't it? * * * Half of them are on two speeds, slow and off."

Staff: "Slow and off."

Salesman 4: "It's true and it's so frustrating. So we go in there. We are very familiar with the hospital and every hospital in Brooklyn. We sort of expedite things here if we can."

Staff: "If there is an emergency, can you help in those situation?"

Salesman 4: "Always, 24 hours a day, 7 days a week, if you need us for anything. Any type of pacemaker, we would be more than happy to help you. Whatever he needs."

Salesman 17: "I'm normally in surgery all day long. I go in, test the pacemaker. Even go over charts where necessary."

Every pacemaker salesman interviewed indicated a good part of their job consisted of assisting physicians in the operating room. Many times, scheduled appointments with salesmen were adjusted "because the salesman had to attend an implant." On several occasions, we interviewed salesmen who had just returned from assisting in a procedure.

From our interviews, and all the other available evidence, it appears the salesman is present at about three-quarters of the pacemaker operations. The presence of the salesman is directly correlat-

ed to the size and nature of the hospital and experience of the physician. The salesman is at least one-third more likely to be present and participate in an implantation that occurs at a community hospital than at a pacemaker center.

One expert, asked to comment on this situation, defined the problem as follows:

> The nub of the problem is this has become an extremely technical operation. Every pacemaker is different, every manufacturer is different. Every device is different. Every model is different. Every programer is different. All this inter-relates in a very critical way when you put one of these devices into a patient. The fact is it is extremely difficult if not impossible to keep up with all the technical minutia if you are a general practicing cardiologist. And in fact, when they come right down to it, most of them can't do it. It's just like a computer. Operating a computer is not a complex task. Anybody can be taught to operate a computer. On the other hand, the smartest computer dataist cannot sit down at the control of a computer he had never seen before and make it do anything. It is not complicated. It doesn't separate the intellectual from the nonintellectual, the good from the bad, or anything. It simply separates those who know it and those who don't. The problem is that the working solution arrived at is to let the manufacturers' representative comes in and provides the technical information.

Staff: "If a cardiologist doesn't know how it works, should he be doing the operation?"

Physician: "No, he should not. That is the way I feel. That is the way most of us feel. It is the only reasonable approach. But the fact is there is no mechanism in this country today to ensure that will take place."

Another of the experts interviewed said:

> I am not morally opposed to the presence of the manufacturer's representative in the operating room. I am morally affronted by the necessity to have the pacemaker's representative in the room. And there is another issue. If you have a manufacturer's representative in the room, you're going to be inhibited in your selection process as you're taking care of the patient. If the electrodes that that manufacturer has are OK but somebody elses are better, you are probably not going to use the slightly better ones, just because of the inhibiting influence of that representative in the room.

OFFICE VISITS

Salesman 14: "When the device doesn't work, the nurse calls me and I come in and reprogram."

Staff: "Isn't that something a nurse could do?"

Salesman: "The nurse would be involved. What you generally would do is give me a call and we would work with the cardiologist or the nurse in the office—that type of thing."

Staff: "Is it hard to do?"

Salesman: "No, it's not hard to do. Anyone can learn reprogramming."

Staff: "Why couldn't the cardiologist do it himself?"

Salesman: "The cardiologist won't do it himself."

DEALING WITH PATIENTS

Salesman 17: "Psychologically, I get a lot of benefit from sitting down with a family after taking part in surgery and explaining, at the M.D.'s request, how that pacemaker is going to work."

Other services provided by the pacemaker salesmen are limited only by the physician's imagination. More common activities included setting up monitoring services, performing educational in-service, instructing office personnel, supplying medicare billing information, and technical guidance related to maximizing medicare reimbursement.

Salesman 7 provided a useful summary: "If you do implants here you are going to need an analyzer, but if you use me, I'll come into every implant and assist the surgeon.* * * I have an analyzer and I can take all the measurements for him. I do that across the street and that's very, very helpful for the surgeons so he doesn't have to get involved in the—and I can run around and get things for him."

Staff: "I missed what you said."

Salesman 7: "I go into the operating room with the analyzer and take measurements. The threshold is a minimum voltage that is needed to pace the patient because that voltage increases as the threshold rises."

Staff: "Is that what you were doing just now."

Salesman 7: "Yeah, I was at ——— Hospital. I had to do one over there. I brought them an analyzer."

Staff: "I see. So you figure out whether or not it's working?"

Salesman 7: "Well, what we have to do is we have to find the minimum of voltage to stimulate that patient, we're on 1 volt. The pacer puts out 5 volts. As time increases, you get fibrosis that build up around the tip, and the minimum then increases from 1 to maybe 2½ so you have to have a safety margin in there."

Staff: "Couldn't the doctor do that?"

Salesman 7: "He could, but my services are available, freeing the doctor up for something else. That's my job."

Staff: "It's a service?"

Salesman 7: "It's a service. Service is very big in this industry. I'm on call—I carry a beeper, of course—I'm on call 24 hours a day. If you have a problem, I'll come in and take care of you."

Staff: "So again you're saying, the programers, what you call an analyzer, you use?"

Salesman 7: "I have the analyzer, I have all kinds of accessories that are needed. Say if you had a battery change from a Medtronic, there are adapters that are needed. I provide all that stuff. There is no charge for all that stuff."

Staff: "What about the followup stuff?"

Salesman 7: "You're going to follow your own patients?"

Staff: "Yes."

Salesman 7: "All right, No. 1, do you have a receiver?"

Staff: "No we don't. We are looking into that now."

Salesman 7: "If you use us I'll provide you with a receiver. That's about a $1,500 piece of equipment. I'll pay for it personally. Actually I split the cost with the firm. It costs me about $750. But then again, that's another one of our services. And not to sound like we're so spectacular, most companies will do that as well. We will provide that for you."

Staff: "What about the transmitter?"

Salesman 7: "The transmitters are free of charge, and they are included with the price of the pacemaker. And even if we discounted them here, you still get the transmitter."

Staff: "As the HMO grows, we will probably be acquiring patients who have pacemakers already implanted."

Salesman 7: "Then we will still give you the transmitters. If you need a couple of extras, I can always run around and get a couple for you. That's no problem."

Staff: "Anything else that we should know in terms of support and what you can do?"

Salesman 7 (addressing a cooperating physician): "You are a cardiologist?"

Physician: "Yes."

Salesman 7: "Have you ever implanted your own pacemaker?"

Physician: "Some. I'm very comfortable putting the leads in. I'm not very comfortable with pockets."

Salesman 7: "OK. We have courses. We will provide courses. We can send you out to California and train you to put in the pacemakers yourself. That would probably save your organization a lot of money. Don't tell any surgeons I told you that. That's a political thing and I'm getting myself in trouble."

Staff: "How long would it take?"

Salesman 7: "Oh, it's usually about a 3- or 4-day course."

How do pacemaker salesmen feel about their role? The response of one salesman was typical: "I love the business. Love being in the operating room. Love the problem-solving. I enjoy making presentations like this. I'm lucky. I make a very nice income and I like what I'm doing."

Chapter 7

A CANDID CONVERSATION WITH A PACEMAKER SALESMAN

Reprinted below is an excerpt from an interview with a cardiac pacemaker salesman. Since the conversation was conditioned on confidentiality, names, dates, and specific references have been changed to protect the salesman's identity. The pacemaker salesman has been involved in the industry for more than 6 years. He has worked for several pacemaker firms. A transcript of the entire interview has been transmitted to the Federal Bureau of Investigation.

Training

Staff: "What is your background?"

Salesman: "I graduated from college in 1970, and sold surgical supplies until I got into this pacemaker field."

Staff: "What kind of training did you receive at that time?"

Salesman: "I got some training from Intermedics. Basically, more than anything else, I learned as I went along. In other words, I learned the basics that I had to know and I've educated myself."

Staff: "What training did you get from Intermedics?"

Salesman: "From Intermedics? They had, basically, it was a brief training session."

Staff: "And what did they tell you? What was the essence of their instruction?"

Salesman: "Basically what they tried to do is make you able to go in on an implant and take the proper measurements for the doctor. I would ask doctors questions, that's the way you learn the quickest, and I'd read up on it."

Payment

Staff: "How were you paid?"

Salesman: "I've worked as a direct representative on salary and commission and I've worked as an independent representative."

Staff: "What's an independent representative?"

Salesman: "The way that Intermedics got started, the guy who was president was an ex-Medtronic rep and, you know, he went out and stole good salesmen from Cordis and from Medtronic. He stole them all. They were all making maybe $8,000, $9,000 a year. Intermedics now has approximately, and I'm going to take a rough guess, has approximately 13 rep companies in the United States. I now get paid a salary commission. Intermedics does not work that way. When you are a representative of Intermedics, you are an independent agent, like insurance men, and you get paid commission only. So Intermedics has 13 what they call manufacturer's repre-

sentatives in the United States. And then there are some, under those 13, there are some that we call sub-reps. On a day-to-day basis their sub-reps daily do go out and make contact with the customers."

Staff: "What do the others do?"

Salesman: "They're basically administrative. Some of them have other lines besides pacemakers, some just have pacemakers. They receive 20 to 35 percent of the sale of the generator. The sub-rep generally gets about half of that. The salesman winds up with one-half to two-thirds of the sub-reps share."

Staff: "Are there any other rewards, compensations, that the sales representatives receive? Do they have, for example, an ownership interest?"

Salesman: "You mean, do they own part of the company, like in common stock? I would imagine all these guys do. I am almost certain, though I can't prove it. I can't show you anything to prove it, but they all own common stock in the company."

Staff: "Do these stock arrangements, as far as you know, or have heard, date back to the initial agreements?"

Salesman: "Yes, way back. The way that the guy who started Intermedics got all these guys away from the other pacemaker companies was, supposedly, he put up large sums of money to get them started, and he gave them stock in the company, supposedly. That's what I heard."

Pacemaker Price

Staff: "Who determines the sales price of a pacemaker?"

Salesman: "They all come with a price list. Me, I hardly ever look at it."

Staff: "Was the price list ever discounted and, if it was, how often?"

Salesman: "To hospitals?"

Staff: "To whomever?"

Salesman: "No."

Staff: "It was sold at the list price. Was it ever sold at more than the list price?"

Salesman: "Never."

Staff: "Was it ever sold at less than the list price?"

Salesman: "Not with my accounts, no."

Staff: "Was the inquiry ever made? Anybody ever say, I want a good price, or I want a better price, or——"

Salesman: "Hospitals never said a word. When I worked for Intermedics, never."

"Enticements"

Staff: "What about the accessories? Do you have the same arrangement with those things as you do with the pacemaker?"

Salesman: "Well there, there's a lot of leeway."

Staff: "There's a lot of leeway?"

Salesman: "OK, basically what you should be doing with every pacemaker patient is they should be getting a transtelephonic transmitter. Then you've got, as I mentioned to you, the receiver in the office. OK? Now those items, what we normally do, to give you

an example, that would be like an enticement to say, 'Doctor, use our pacemaker and we'll give you a receiver that you could have in your office for your patients.' "

Staff: "Are those expensive?"

Salesman: "Yeah, those cost about $2,000."

Staff: "And you could give those away to a doctor."

Salesman: "You just don't—you don't have 10 of those in your car. They are expensive. What you would have to do is, I'd call up Frank, who would call up the rep, and I'd say, 'Look, this guy will switch over. But you have to do this. OK? Because there is no reason right now for him to switch.' It's just an example."

Staff: "So that's one example. Are there other things like that you can use as an enticement, as you say, or is that the only one?"

Salesman: "Well that's, I would say that's the biggest. That's a device that he can use and he really needs."

Staff: "What about the programer?"

Salesman: "OK, the programer. If a doctor puts in most any pacemaker, he has to have a programer in his office. Or if he doesn't, I have to have one in my car, so if this patient's rate has to be changed he can call me up."

Staff: "Is that sold, or is that discounted, or is that something that the doctor——"

Salesman: "We consign that to either the hospital or the doctor's office. We don't give it to him. We don't sell it to him. We just bring it in and say this is for your use on this current technology. Now 2 years down the road this technology could be obsolete. We bring in the new one which would work on the new pacemakers."

Staff: "What else?"

Salesman: "Well, the transtelephonic transmitters which we give to the doctor. We give three or four of those, in terms of accessories, that's basically——"

Staff: "Beyond accessories, what other enticements were there?"

Salesman: "They have the followup service from the company."

Staff: "What is that?"

Salesman: "Basically, Intermedics, at their home office, has a registered nurse there at all times, plus they have, I believe on staff, they still have a doctor, an M.D. If a doctor in, let's say Des Moines, calls Freeport and says, I think there's a problem with this pacemaker, and they would transmit it over the phone lines, and Intermedics would look at the cardiac electrogram and say to the doctor, that pacemaker is fine, or that pacemaker is not working properly, and they would then send him a followup report within 24 hours."

Staff: "Was that an expense to him?"

Salesman: "That was free. That was an enticement."

Travel As An "Enticement"

Staff: "Let's take it one step down. What other kinds of enticement are there?"

Salesman: "What do you mean, specifically?"

Staff: "Well specifically, we've heard stories and seen reports that there are trips that are taken, fishing excursions, plane rides to the plant——"

Salesman: "That's true."

Staff: "What happens and how does it happen?"

Salesman: "Well, OK, to give an example, there is a doctor who uses, let's say Medtronic. And he does, let's say, five pacemakers a month in his practice. And you're the Intermedics rep, and have gone in there and you've tried to sell them your product, and that's not working. He says, they are all the same, leave me alone. You try the receiver. You say, hey, use our receiver. You can call Freeport, it's free of charge. That doesn't work. So then you might say, hey listen, have you ever seen a pacemaker built before? And he would say, maybe, no, I haven't. How would you like to go to Freeport and visit our production facilities? And what we would do sometimes, is ask, hey, do you like to fish? And he would say, yes. He would say, there is a boat in Texas. What normally would happen is you go to the plant, say on Friday, take the plant tour, and then Saturday you go fishing. And then go back home Saturday night or Sunday."

Staff: "How does he get to Texas?"

Salesman: "There used to be two ways, but now there is only one. Intermedics has a Lear jet. When Al was alive, if you wanted that Lear jet he would fly it to you and back. When Al died, the company changed. He (the new president) said you guys aren't going to use that Lear jet just like that. And if you want to, I'm charging you, the rep, a couple of hundred an hour. So some reps bought their own planes. I would say this doctor wants to go to Freeport, and I'd arrange the date with the rep. And they would arrange the plant tour with the guys in Freeport. We all get on the plane and fly to Freeport."

Staff: "The rep would go with the doctor?"

Salesman: "I would. They fly us to Freeport. They put us up at either, at what is a—there aren't too many good places in Freeport. They put us up at the Hilton or there is a country club. And then the next day you go on a plant tour. And that would last about 3 hours. You'd have lunch, in the corporate dining room. Then the next day, if they like, if they wanted to, they'll go on the boat. It's a 52-foot Hatteras."

Staff: "What happens if you don't like fishing, and you don't like boating? Is there something else you can do?"

Salesman: "Well, during the wintertime, if you like hunting, they have a hunting preserve down there, and they take them hunting."

Staff: "It's a company hunting preserve."

Salesman: "Yeah."

Staff: "Have you ever heard of gambling junkets?"

Salesman: "I've heard of it, but I never did it."

Staff: "If the doctor wanted to bring his wife along, or his girlfriend, is that OK?"

Salesman: "Sure."

Staff: "How often was the boat busy?"

Salesman: "During the summertime, there is an allotment. Most reps have the boat maybe 15 to 30 days during the summer. Everyone had certain dates. So you would have to call up in advance, and if that date was open for you, or your rep, you might get it. It

got so popular, they bought another boat, and they put it in Fort. Lauderdale."

Staff: "Was that boat, or the boat in Texas, used for any other reasons?"

Salesman: "Besides fishing? Not to the best of my knowledge."

Staff: "What about the planes? Was there any other corporate purpose for the planes?"

Salesman: "Oh no."

Staff: "They were for the exclusive use of the sales force?"

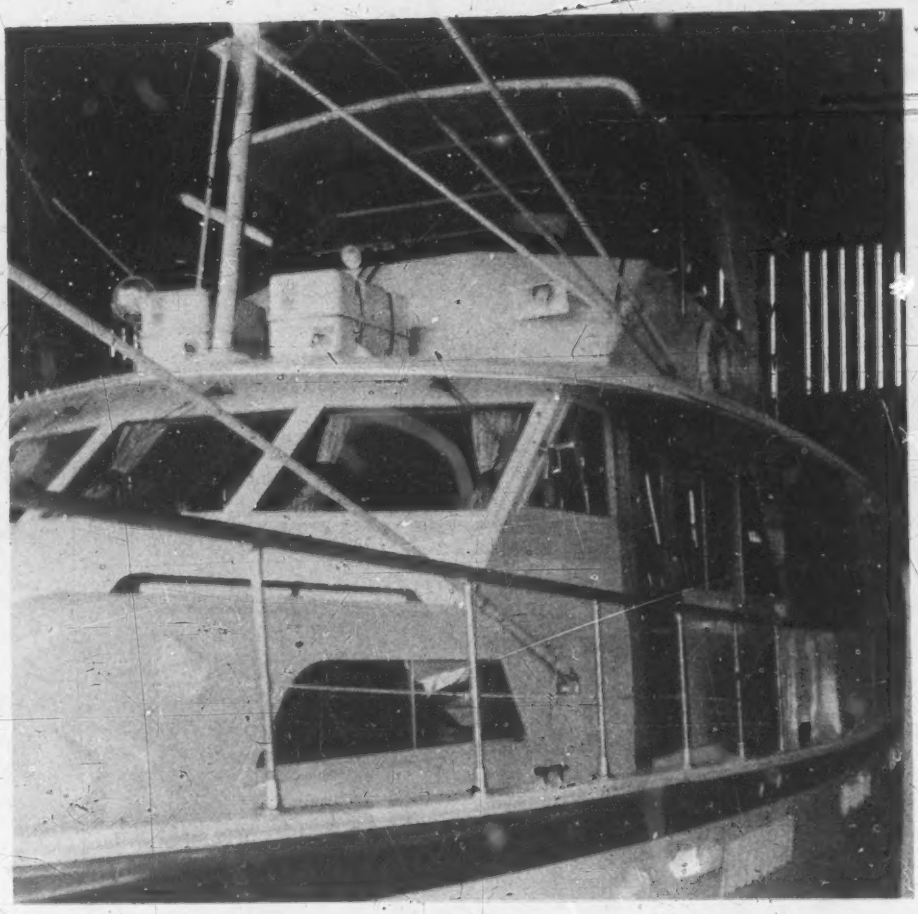
Salesman: "The sales force. Maybe, maybe, maybe the guys in Texas would hop in their Lear jet and go down to Silicone Valley and look at a design chip. Maybe."

Staff: "What was the other thing you said that plane was used for?"

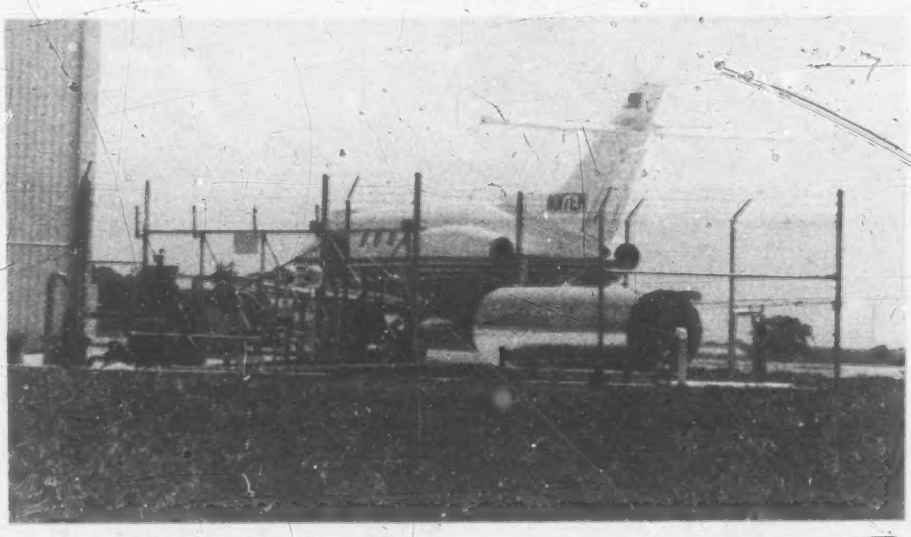
Salesman: "I'm sure they use it for their vacation."

Staff: "Personal?"

Salesman: "Personal, yeah."



"The Good Times"—a 55-foot yacht allegedly used by Intermedics representatives and implanting physicians.



One of a number of airplanes allegedly expensed to the sales department of Intermedics.

Salmon Fishing in Alaska

Staff: "What about a doctor or someone like that. Would they get a vacation, ride on the plane? If I wanted to go to the Bahamas, could I get a ride down there?"

Salesman: "I'm sure you could."

Staff: "Do you know specific instances?"

Salesman: "I never did that. But I know there are instances where they used that plane, they took doctors on vacation that never went through the plant."

Staff: "To go where, for example?"

Salesman: "Salmon fishing in Alaska, for example. That's an example. White water rafting on the Colorado. You have to remember that probably the guys that used that plane for vacations, they are probably Intermedics accounts already. You just don't get a doctor who never used your product, and do that for him. That's not your norm. Usually the guys that they send on those little trips are big clients, and it's some sort of reward."

Staff: "What level of use do you have to achieve before you get that kind of——"

Salesman: "I would say if you're an Intermedics account for 2 years, and you've been doing 8 to 10 pacemakers a month, you would probably get the trip you asked for. A lot of times if they were afraid of losing the account, I know those two guys, if they were afraid of losing an account, they'd personally fly down and see that doctor."

Staff: "Why? Do you mean he was going to go to somebody else?"

Salesman: "Another pacemaker manufacturer."

Staff: "But why, was it a better product or what?"

Salesman: "That I don't know. Probably they were getting a greater enticement, knowing that particular doctor."

Stock

Staff: "Who else would have, if anyone, an ownership interest in the company?"

Salesman: "What do you mean by that?"

Staff: "You said the reps have stock."

Salesman: "Sub-reps."

Staff: "Sub-reps. What about one of these big doctors, would they have an ownership interest?"

Salesman: "Well, I'm sure you've heard, that through the years, that these doctors have gotten stock."

Staff: "How frequently do those people have an ownership interest in the company?"

Salesman: "Some of them do."

Staff: "Ballpark figure?"

Salesman: "There's always a percentage of the doctors you deal with that have stock in any company."

Staff: "They might buy some of their own?"

Salesman: "Yeah. They might buy it on their own. But with Intermedics, I would say that if you talk to any sales rep in the pacemaker business, they will tell you, hey, that doctor got stock in Intermedics as an enticement."

Staff: "One of the things we hear is, it's much easier for somebody to sell Intermedics products, even some of the more expensive products, because there are these built-in incentives."

Salesman: "Incentives, that's right."

Staff: "How much of that is going on?"

Salesman: "With Intermedics, I'm just going to guess and say, I'd say a good 30 percent."

Staff: "Thirty percent of the total?"

Salesman: "Sure, their doctors have stock in the company."

Staff: "And what do you know, if anything, about the conditions of the purchase of that stock?"

Salesman: "I know of one instance. A doctor who got a large share of the Intermedics stock."

Staff: "When did this occur?"

Salesman: "1980, about May."

Staff: "So as late as 1980 it was still possible."

Salesman: "Still goes on. The rep wanted to get that account, because this particular doctor pumps in a lot of pacemakers. And he went to this doctor and I guess he said look, you know, if you use our units I'll get you some stock. They kept on working on it and I think he got the stock, probably got it either third or fourth quarter of 1980."

Staff: "What do you mean he was pumping them in? How many should he have put in, and how many did he put in? How far over is he?"

Salesman: "I think it's almost double."

Staff: "Twice as many?"

Salesman: "Yeah. It's a joke. It's a joke. I guarantee you every salesman in the country knows this guy. He's a joke."

Staff: "What was the agreement? Stock passed hands to this doctor so——"

Salesman: "That he would use Intermedics pacemakers."

Staff: "Is there an agreement at that point, a signed contract?"

Salesman: "No, oh no."

Staff: "What is the agreement?"

Salesman: "It's a verbal agreement. But I think basically what he did, this one doctor from what I see, is, he made a lot of promises to them. He got the stock, and then maybe about 6 months later he basically gave it to them up the old shaft. He didn't live up to his end of the deal. And it's verbal, so there is nothing you can do about it."

Staff: "Who in Texas was involved?"

Salesman: "I would say it would probably start off with maybe somebody in sales, the vice president of marketing or sales, and then it would spill over to some of the executive officers, and then to the legal department."

Staff: "So then it would be a corporate decision."

Salesman: "Sure, they're all in it."

Staff: "What did he pay for his stock?"

Salesman: "I have no idea."

Staff: "Did he pay market?"

Salesman: "I wonder. I don't know if he got it free, or he paid market price for it. I don't know."

Staff: "If he paid market, why would he go to all the trouble of going through Texas?"

Salesman: "I don't know."

Staff: "Would you ever give a doctor cash?"

Salesman: "No, I think most of the doctors, if you tried, that they would probably throw you out of their office, including him, I mean he wouldn't want it that obvious."

Chapter 8

FEDERAL TRADE COMMISSION ACTIVITIES

The Federal Trade Commission has conducted two extensive staff investigations of the pacemaker industry. The FTC's focus has been questions of competition (antitrust) and warranty.

A. Bureau of Competition Investigation

In 1978, the FTC's Bureau of Competition initiated an inquiry of structural and behaviorial aspects of the industry. Of primary concern, was Medtronic's dominance of the market, and allegations that antitrust laws were being violated.

At that point in time, the pacemaker market was dominated by four firms: Medtronic with a 46 percent share of the domestic market; Cordis with a 16.7 percent share; CPI with a 12 percent share; and Intermedics with a 10 percent share.

On December 8, 1979, staff attorney Patricia Bangert, Bureau of Competition, summarized the findings of the staff investigation in a memo to Alfred F. Dougherty, Jr., Director, Bureau of Competition, FTC (appendix Q).

The findings of the FTC investigation in 1978 nearly parallel those of the committee some 4 years later. The FTC found:

—The pacemaker industry is highly competitive, although price has never played an important part in consumer choice due to the fact that a third party usually provides the device.

—Manufacturers of pacemakers have been offering lifetime warranties that do not cover full replacement costs. In at least some cases, there was evidence the warranty was being communicated to the physician but not patients.

—Allegations that certain pacemaker manufacturers have given or are giving bribes to physicians to induce them to implant pacemakers.

—Alleged bribes consisted of money, stock in the company, land, free trips, use of credit cards, and fees for work never performed.

—The problem was widespread, "The nature and size of the reported bribes (stock, land, etc.) suggests corporate approval rather than a case of unrelated acts of overly aggressive salesmen."

—Evidence that monitoring devices, receivers, and transmitters were routinely given away, constituting an illegal tie-in.

The memo concluded with a recommendation that the antitrust allegations be dismissed, that the warranty matter be pursued by the Dallas regional office, and that allegations of commercial bribery be forwarded to the Department of Justice for investigation.

The FTC investigators had obtained the names of doctors and administrators allegedly involved in bribery, and at least one case where a physician admitted acquiring stock, but were unable to proceed without process. "To go forward," the FTC concluded, "would require process powers to reach medical firms' records and perhaps personal records of salespersons and physicians * * *." The next logical step would be to attempt to prove that "named" physicians did, in fact, accept some kind of bribe to implant certain brands of pacemakers. This, though, is a difficult task, requiring many more resources and an expertise in criminal-type investigations. Accordingly, staff recommended the matter be forwarded to DOJ for investigation of specific allegations of bribery.

There is no evidence the material was actually referred to the Department of Justice for action.

B. The Warranty Issue

In February 1977, Willie A. Meadows of Houston, Tex., was admitted to the Eastway General Hospital in Houston with a diagnosis of possible heart block. Twelve days later, Mr. Meadows was released with a pacemaker and a 10-page hospital bill that totaled $7,710.95.

A summary of Mr. Meadows' bill is reprinted below. The Medtronic pacemaker he received accounted for $2,046 of the $2,323.75 total ascribed to central supply and dressings.

X-CY HOLDER

ADMITTING DIAGNOSIS: POSSIBLE HEART BLOCK — DISCHARGE DIAGNOSIS: 4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE — DATE

SELF

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION			CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
	SUMMARY OF CHARGES							
	ACCOMMODATION	DAYS	RATE					
	SEMI PRIVATE	4	73.00			292.00	0.00	292.00
	ICU/CCU	8				1404.00	0.00	1404.00
	OPERATING ROOM					156.00	0.00	156.00
	RECOVERY ROOM					27.00	0.00	27.00
	IV SOLUTIONS					132.50	0.00	132.50
	EMERGENCY ROOM					20.50	0.00	20.50
	LABORATORY					1140.50	0.00	1140.50
	EKG					358.50	0.00	358.50
	EEG AND ECHO					74.00	0.00	74.00
	RADIOLOGY-DIAGNOSTIC					197.50	0.00	197.50
	PHARMACY					501.20	0.00	501.20
	ISOTOPES AND SCANS					193.00	0.00	193.00
	ANESTHESIOLOGY					56.00	0.00	56.00
	INHALATION THERAPY					767.50	0.00	767.50
	PHYSICAL THERAPY					67.00	0.00	67.00
	CENTRAL SUPPLY AND DRESSINGS					2323.75	0.00	2323.75
	OTHERS					0.00	0.00	0.00
	TOTAL CHARGES					7710.95	0.00	7710.95
	CASH PAYMENTS AND AR ADJUSTMENTS					0.00	0.00	0.00
	TOTAL					7710.95	0.00	7710.95

IMPORTANT

THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

[illegible] INCOME TAX DEDUCTION. PROMPT PAYMENT WILL ASSURE [illegible] PROTECTION. [illegible]

DEDUCTIBLE → 0.00 0.00

7710.95 0.00 7710.95

MEDENCO Inc.

MDX-79

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Eleven months later, Mr. Meadows was readmitted for replacement of a defective pacemaker, guaranteed by the manufacturer for 30 months. This time, Mr. Meadows' bill totaled $3,710.10, and covered 6 days of hospitalization. A summary of Mr. Meadows' replacement charges is reprinted below. Again, pacemaker costs are carried under central supply, accounting for $2,304 of the $2,377.80 total.

DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
SUMMARY OF CHARGES					
ACCOMMODATION DAYS RATE					
SEMI-PRIVATE 5 82.00			410.00	410.00	0.00
OPERATING ROOM			145.00	145.00	0.00
IV SOLUTIONS			28.00	28.00	0.00
LABORATORY			77.00	77.00	0.00
EKG			304.50	304.50	0.00
RADIOLOGY-DIAGNOSTIC			42.50	42.50	0.00
PHARMACY			274.60	274.60	0.00
ANESTHESIOLOGY			50.50	50.50	0.00
CENTRAL SUPPLY AND DRESSINGS			2377.00	2377.00	0.00
OTHERS			0.00	0.00	0.00
TOTAL CHARGES			3710.10	3710.10	0.00
CASH PAYMENTS AND AR ADJUSTMENTS			0.00	0.00	0.00
IMPORTANT			DEDUCTIBLE →	124.00	124.00
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY	WHEN PAID, YOUR HOSPITAL EXPENSES NOT COVERED BY INSURANCE MAY BE SHOWN ON THIS DESCRIPTION OF CHARGES		3710.10	3586.10	124.00

During the next few months, Mr. Meadows wrote the manufacturer, Medtronics, the FDA, the Texas attorney general, and the FTC, complaining that costs associated with the pacemaker replacement should have been reimbursed under the provisions of the pacemaker warranty. The admitting diagnosis carried on his second hospital bill is "pacemaker failure."

The Texas attorney general's office responded that a complaint file had been opened on the matter and suggested, "If your claim is substantial, you may wish to consult a private attorney while we process your complaint." Medtronic responded they were unable to consider the unit for credit since the unit, an Xyrel model 5972, appeared to be functioning on subsequent analysis within tolerances established by Medtronics. The Food and Drug Administration responded, an investigator would be in contact to discuss the failure of the pacemaker and suggested the warranty might be of interest to the FTC (appendix R).

In May 1978, Mr. Meadows wrote the Federal Trade Commission restating his concern:

> This pacemaker carried a 30-month warranty and was removed after 11 months of service, leaving 19 months of warranty that Medtronic won't make good * * * I feel I am due 19 months' rebate at $68.20 per month, a total of $1,295.30.

The Dallas regional office initiated an investigation on September 1, 1978. The basis of the review is stated in a memo dated June 19, 1978, to Juereta P. Smith, director, Dallas regional office, from Consumer Protection Specialist Andrew Armstrong:

Proposed respondent offers a warranty to the patient which states, "Medtronic shall have the exclusive right to analyze any generator returned for credit and to determine, in its sole discretion, whether such generator required replacement for any of the reasons designed in this subsection 5(1)(d)." The Commission in its final interpretations of the Magnuson-Moss Act, part 700.8, advised, "A warranty shall not indicate in any written warranty or service contract, either directly or indirectly, that the decision of the warrantor, service contractor, or any designated third party, is final or binding in any dispute concerning the warranty or service contract. Nor shall a warrantor or service contractor state that it alone shall determine what is a defect under the agreement. Such statements are deceptive since section 110(d) of the act gives State and Federal courts jurisdiction over suits for breach of warranty or service contract.

These terms in proposed respondent warranty could be described as a deceptive warranty under the Magnuson-Moss Act, section 110(5)(c)(2), in that a representation is made that the warrantor's decision is final and binding whereas the Magnuson-Moss Act, section 110(5)(d), gives State and Federal courts jurisdiction over such matters. Therefore, staff believes there is a per se violation of the Magnuson-Moss Act by proposed respondent * * * Staff also considers an injury to occur if proposed respondent retains the replaced pacemaker without coming to an agreement with the third-party insurer or patient as to the value of the returned pacemaker and the failure of proposed respondent to pay such value to third-party insurer. Each of these costs probably substantially increase the cost of providing medical services and devices within the United States.

The FTC regional action was buttressed by a number of complaints similar to Mr. Meadows' directed to the Food and Drug Administration, then HEW Secretary Califano, and the FTC. In each case, medicare and the individual were asked to absorb costs associated with the replacement of defective devices.

One physician, Dr. Arnold Wagner of Evanston, Ill., indicated he had felt compelled to replace four defective pacemakers at an average cost to medicare of about $3,000 each. Dr. Wagner characterized the restitution offered by the manufacturer as, "fractional at best. Their concept of product liability appears to include sharing it with consumers to a very considerable extent. Through the agency of medicare the taxpayer has been maneuvered into picking up perhaps two-thirds of the loss."

FTC workpapers identify a number of problems associated with pacemaker warranties:

—Manufacturer advisories were not retroactive, so that patients were not reimbursed for defects discovered before the manufacturer announced the problem.

—Replacement credits, to the extent they were available, were limited in amount and only applied toward the purchase of a second unit made by the same manufacturer.
—Some firms had excluded batteries from the provision of warranty.
—Often defective devices were not returned to the manufacturer for credit; the costs were passed on to third-party payers.
—In many cases, an otherwise valid claim under warranty would automatically be disclaimed if the patient is covered by insurance.

The regional FTC was active through at least part of 1979. For reasons unknown, the investigation lapsed after the 3 years of interest. There is no indication of a closing action or attempted resolution on file.

Chapter 9

VETERANS ADMINISTRATION ACTIVITIES

The Veterans Administration implants about 3,000 pacemakers a year at 90 pacemaker centers. Since the first implants in the early 1960's, 25,000 veterans have received pacemakers at VA facilities.

A. Inspector General Audit

In late September 1975, following the receipt of serious allegations of impropriety at VA centers with regard to pacemaker procurement policy, the VA IG initiated a review of, "Procurement and Monitoring of Pacemakers." The audit had the following objectives:

(1) Determine the VA's vulnerability to fraud and abuse in the pacemaker program.

(2) Determine if there are any indications of fraud and abuse in the pacemaker program.

(3) Determine whether the VA is paying the lowest possible price for the pacemakers purchased.

(4) Determine the adequacy of guidelines and controls for acquiring pacemakers and monitoring services; and

(5) Determine the adequacy of guidelines and controls for monitoring pacemaker patients and processing pacemaker recalls.

The report released in February 1980, concluded:

> Specific instances of fraud in the pacemaker program were not identified during the audit; however, the pacemaker program is vulnerable because controls are not adequate for the requisition, receipt stocking, and disposition of pacemakers. Three specific instances of serious irregularities in the procurement and monitoring of pacemakers are under investigation. The VA could reduce its pacemaker expenditures by purchasing through competitive bid precedures; by obtaining and collecting credits for removed pacemakers; and by recycling pacemakers, if appropriate. Service to pacemaker patients can be standardized among medical centers by defining the VA's responsibility, determining appropriate monitoring procedures and by improving the communication of recall information, and establishing a system to identify patients affected by recalls.

B. Corrective Action

The VA Inspector General recommended the following corrective actions: Developing a pacemaker registry at each medical center and a central registry at central office; establishing a prosthesis profile for each pacemaker patient who is currently a VA patient; determining that all veterans who have received pacemakers must

have adequate followup surveillance either under VA auspices, or by referral to another acceptable health care provider; requiring direct clinical surveillance for all patients during the first weeks after implantation, developing surveillance plans; including both professional and administrative staff in pacemaker selection; and, including supply service when pacemaker exchanges are made with the manufacturer.

VA implementing regulations, circular 10/81/97 (June 1981), outline the policy revisions emerging from the VA audit. These revisions include:

—Establishing certain of the VA's medical centers as pacemaker centers and requiring all other VA facilities refer veterans to these centers for pacemaker services.

—Developing a schedule of approved devices.

—Establishing monitoring schedules to assess the pacemaker's performance at least twice a year, but more often as needed, and contracting for these services with a limited approved list of vendors where the services are not provided directly by the VA. Monitoring services provided by manufacturers are expressly prohibited.

—Establishing a cardiac pacemaker registry to track pacemaker performance and the impact of the device on the patient. The VA registry currently lists 10,000 patients.

—Establishing negotiated rates for the purchase of pacemakers and related accessories.

—Implementing strict warranty provisions that include provisions crediting the full purchase price of the device to the purchase of any other suitable device, including that of a competitor.

In May 1981, the results of these remedial actions were assessed in an internal memorandum. The memo indicates purchase discounts had been obtained from 10 to 30 percent below the commercial price. Savings on particular pacemakers ranged from a low of $98 to a high of $839.

The average saving per company was detailed as follows: Biotronik, $284.50; Cardiac Pacemaker, $517.16; Coratomic, $794.00; Cordis, $410.55; Intermedics, $454.33; Medtronic, $453.33; Pacesetter, $431.90; and Telectronics, $351.05.

Comparable prices were consistently offered to the committee in our discussions with salesmen when it became apparent that price was a consideration. In addition, the price offered the committee included the cost of ancillary devices offered to induce business, and the cost associated with the pacemaker salesman's services—estimated by some experts at 5 to 15 percent of the retail price.

Chapter 10

CONCLUSIONS

The committee's review identified a number of significant problems related to the purchase and use of pacemakers for medicare beneficiaries. Among these concerns are issues of performance, cost, warranty, professional qualifications of implanting physicians, utilization, and allegations of criminality.

Several of these problems have been previously identified by investigations of the Securities and Exchange Commission, Federal Trade Commission, Veterans Administration, and the General Accounting Office. Despite these activities, the problems persist.

It appears the fundamental cause of this systemic failure is related to the fragmentation of Federal responsibility, the failure to communicate findings, even when the need for communication is recognized, and the absence of leadership from the Department of Health and Human Services.

Given the pervasiveness of these problems and the fragmentation of Federal regulatory activities, the best hope of resolution lies in a concerted effort. The Department of Justice, Securities and Exchange Commission, Internal Revenue Service, and the Federal Bureau of Investigation should establish a joint task force to address the allegations of criminality.

Congress should consider:

—Establishing an alternative purchase mechanism for pacemakers, if even on a demonstration basis. Contract purchasing and negotiated rates should be explored.

—Establishing a pacemaker registry within the FDA or HCFA to track device performance, protect beneficiaries, and insure the proper collection and credit of manufacturers' warranties.

—Consider establishing performance bonds for pacemaker firms to insure the collection of warranties in the event of company failure.

The Department of Health and Human Services should:

—Develop pacemaker utilization screens.

—Review and reduce physician payment screens, particularly those of physicians involved in operative procedures associated with pacemaker implantation.

—Review and reduce medicare transtelephonic monitoring frequency schedules and payment levels.

—Study proper pacemaker indices for those over age 65 and the need for and benefit of sophisticated state of the art pacemakers.

—Consider the establishment of requirements for pacemaker procedures and facilities similar to those employed for CAT scanners, i.e., a system of centralized service where specific expertise can be developed and a minimum level of use maintained.

—Require intermediaries to establish a payment edit keyed to pacemaker replacements to assure proper warranty credits.
—Prohibit the return of explanted devices purchased for medicare beneficiaries to manufacturers.
—Prohibit warranties conditioned on replacement by the same company that manufactured the defective device.

The Food and Drug Administration should:

—Reconsider mandatory reporting requirements for product failures.
—Insure the propriety of clinical testing procedures.
—Develop procedures for the proper evaluation of devices explanted from medicare beneficiaries.

The Veterans Administration should renegotiate its purchase contracts for pacemakers. Although significant savings over medicare payment levels have been achieved by the VA, greater savings are possible.

The Securities and Exchange Commission should investigate the apparent impropriety in the transfer of stock in pacemaker firms for less than value as an inducement to do business.

Chapter 11

GLOSSARY OF PACEMAKER TERMS

ATRIA.—The two upper chambers of the heart. The right atrium receives unoxygenated blood from the body, the left atrium receives oxygenated blood from the lungs.

A-V (ATRIOVENTRICULAR) NODE.—A special conduction pathway between the upper and lower chambers of the heart. It receives the electrical impulse from the upper chamber and passes it downward into the lower chambers.

BRADYCARDIA.—An abnormally slow heart rate, generally under 60 beats per minute in the awake individual.

BUNDLE BRANCH BLOCK.—A blockage of one of the specialized conducting pathways within the lower chambers of the heart.

CAPTURE.—When a pacemaker impulse succeeds in causing the heart to beat or contract.

CARDIAC OUTPUT.—The amount of blood pumped by the heart per minute.

DEMAND.—A type of pacemaker that senses the natural activity of the heart and supplies electrical impulses only when the natural heart rate falls below a certain level.

DIASTOLE.—The relaxation of the heart between contractions.

ELECTROCARDIOGRAM.—Often called EKG or ECG, it is a graphic record of the electric currents produced within the heart.

ELECTRODE.—The wire that conducts electrical impulses to the heart and electrical signals from the heart back to the pulse generator.

ENDOCARDIAL.—Refers to the inner layer of the heart. An endocardial electrode is one that is passed via a vein to the internal surface of the heart.

EPICARDIAL.—Refers to the outer layer of the heart. An epicardial (or myocardial) electrode is attached directly to the outer surface of the heart.

FIBRILLATION.—Rapid, uncoordinated contractions of the heart muscle occurring when the individual muscle fibers take up independent, irregular contractions.

FIXED RATE.—A type of pacemaker that sends out impulses at a set rate regardless of the heart's intrinsic rhythm.

HEART BLOCK.—A condition in which the electrical discharges of the upper chambers of the heart are not transmitted normally to the lower chambers.

HERMETIC SEAL.—A process by which the power cell and circuitry of the pulse generator are sealed within a metal container so that they cannot be penetrated by body fluid.

LEAD.—The insulated, flexible wire that carries electrical impulses from the pulse generator to the heart. The electrode on

the tip of the lead may be lodged inside the heart by threading the lead through a vein, or it may be attached to the muscle tissue of the heart's outer surface.

LITHIUM-IODINE.—A long-life cell currently in wide use as a power source for pacemakers.

PROGRAMABLE PACEMAKER.—A type of pacemaker that can be adjusted electronically from outside the body. The rate of pacing and, with many models, several other important output functions of the pacemaker can be adjusted without surgery.

PULSE GENERATOR.—The part of the pacemaker (the small metal cast) that contains the electronic circuitry and the power cell, and that produces the electrical impulses carried to the heart by the lead.

S-A (SINOATRIAL) NODE.—The special nerve center in the upper right chamber of the heart that normally initiates each beat.

SENSE.—The ability of a pacemaker to recognize the electrical impulse of a heartbeat.

SINUS RHYTHM.—The normal heart rhythm. An electrical impulse originating in the right atrium is passed into the ventricles, causing them to contract 60 to 100 times per minute.

SYSTOLE.—The contraction of the heart that forces blood though the arteries.

TACHYCARDIA.—An abnormally rapid heart rate, usually over 100 beats per minute.

THRESHOLD.—The lowest amount of electrical energy necessary from a pacemaker stimulus to cause the heart to contract.

TRANSVENOUS.—A term meaning "through a vein." Endocardial leads, which are designed to work inside the heart, are passed through a vein to the heart's interior.

VENTRICLES.—The lower chambers of the heart. There are two, the right and the left ventricle. These chambers are responsible for the actual pumping of blood to the lungs and the rest of the body.

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APPENDIX A

Hot operators: Sales to the heart surgeons

By Arthur Howe
Inquirer Staff Writer

On many workdays, Peter McGovern dons a drab-green smock, lead apron, plastic shoe covers and a linen mask. Then he joins a team of heart specialists — a cardiologist, a cardiac surgeon and an anesthesiologist — in an operating room to implant an electronic pacing device in a patient's fading heart.

Though lacking any formal medical training, McGovern, 47, is a critical element in the delicate operation. He is the pacemaker salesman.

"I'm there in case anything goes wrong," says McGovern, who lives in Medford, Burlington County. "The surgeons want someone to look at the patient's EKG (electrocardiogram — a graph showing the patient's heart contractions) or to help them program the pacemaker. The doctors need to take a course in computers to understand the new pacemakers. They don't have time."

In many of the nation's 120,000 operating rooms, ever-growing numbers of pacemakers are implanted every year — with the technical aid of salesmen. Pacemaker sales this year are expected to jump more than 10 percent from the 89,000 that were implanted last year.

The trend has caused some physicians to wonder if too many pacemakers are being implanted in too many patients, in part due to a growing tendency of doctors to lean on new technology — provided with the eager assistance of pacemaker salespeople — as an easy solution to a patient's medical problems.

The pacemaker salesmen vigorously defend both the utility of their products and their role in the operating room.

And doctors who are unable to stay abreast with the technological explosion of multi-programmable heart pacemakers — some of which are

(See PACEMAKERS on 14-A)

PACEMAKER SALESMAN Peter McGovern (right) takes his post in an operating room at West Jersey Hospital in Camden.

Courting the surgeon: How pacemaker sales representatives . . .

PACEMAKERS, from 1-A

able to mimic the human heart in more than a trillion different rhythmic combinations — are continuing to turn in increasing numbers to industry representatives for training and technical assistance.

The salespeople's operating room task is to help the physicians program the integrated electrical circuits of the lighter-than pacemakers that send mild electronic shocks to stimulate contractions of the heart muscle.

That support role is the most visible aspect of the tight-knit relationship between cardiologists and thoracic surgeons and the pacemaker representatives. It is a working relationship built on considerable trust and mutual respect, as well as the sharing of financial rewards that can push the salespeople's salaries into the six-figure and even seven-figure range.

"It's like mom, the flag and apple pie," said Steven Link, a salesman for Intermedics Inc., a Texas-based pacemaker firm. "We make a good living, the doctor makes a good living and the patient does better."

Nevertheless, studies conducted recently at Brooklyn Hospital in New York and at Harvard Medical School's Peter Bent Brigham Hospital have concluded that some physicians are unnecessarily prescribing pacemaker implants for certain conditions and, in the process, swelling their incomes — and those of the pacemaker sales representatives — by millions of dollars.

One critic, Dr. Peter Kowey of Harvard Medical School, removed 16 pacemakers in recent years from a group of 32 patients whose doctors had prescribed the devices to correct sluggish heart rates. He concluded that 30 percent of the nation's implants for slow heart rate are unwarranted and cost health insurance programs an estimated $100 million a year in unnecessary expenses.

"We don't know for sure how widespread the problem is," he said. "It could be much worse."

In an abstract published in the medical journal Clinical Research, Kowey wrote: "In addition to the morbidity of unnecessary pacemaker implantation, there is also involved a substantial misuse of health care dollars."

Not surprisingly, such talk has sent shock waves through the pacemaker industry, which has seen its market grow to sales of approximately $600 million in 1980. The manufacturers argue that a pacemaker implant is a safe, relatively low-cost solution to a range of heart problems.

"It's clearly a judgment call for the physician," said Ronald Schaefer, president of Pacesetter Systems Inc., a California manufacturer. "But I get so upset thinking about the astronomical number of people walking around who would be so much better off and improve the quality of their life with a pacemaker."

Said John Boettiger, director of marketing research for Intermedics: "If a doctor does a little more than necessary, is that so bad? There are a lot of safety things done in a hospital that don't need to be done."

Although the practice of swimming nonmedical personnel into operations appears widespread — pacemaker representatives say they attend 60 to 80 percent of all implants — it is discounted by some prominent cardiologists.

"I think it is wrong. It is not ethical to allow a technical person to assist with an operation," said Dr. Victor Parsonnet, director of surgery at Beth Israel Hospital in Newark, N.J., and one of the authors of the American Medical Association's guidelines on pacemaker implants. "If a doctor doesn't know how to use his tools, he shouldn't be putting in pacemakers."

While many cardiologists have conceded that there is room for abuse in pacemaker sales practices, most of those interviewed said that most pacemaker salespeople provide a professional, much-needed support service.

The salespeople maintained that in many operating room situations they are at least as qualified to help avert potential complications involving their equipment as the physicians.

The pacemaker salespeople gave two reasons: While many cardiologists might attend one pacemaker implant a week, a high-volume salesman might witness 15. And most experienced salesmen know their equipment's technical abilities much better than the physicians do.

Occasionally, some salespeople said, doctors ask them to perform a variety of specialized tasks, including helping them connect the pacemaker to the patient's heart.

"Believe me, I've done it all," said one Southern California pacemaker salesman, who asked not to be named. "Doctors don't talk about it for obvious reasons."

Dom Kowey, the critic at Harvard, said that "pacemaker salesmen should be congratulated for providing their service. I would not be surprised if there isn't some abuse, but there is no way to quantify it. Mostly these guys are very honest."

Dr. Murray Miller, a cardiologist at Quakertown Hospital and Allentown & Sacred Heart Hospital Center, agreed. "The physician is not an engineer. With pacemakers it's mostly a question of mechanics. The pacemaker salesman is supposed to know that equipment."

The pacemaker salesman's crucial role has brought him rich compensation. Annual gross commissions of $100,000 are considered average at many companies. A few salesmen at aggressive companies like Intermedics gross between $200,000 and $1 million each year.

Intermedics' New England representative, John Temple, said he has a 27-member sales force in the New England area that grosses annual commissions of $20 million to $25 million.

A salesman's financial success hinges on his ability to cultivate the doctor clients, typically a hospital's one or two cardiologists or thoracic surgeons who decide which pacemakers to purchase. It is a fiercely competitive business.

In Miami, 26 pacemaker salespeople compete for the attention of 18 surgeons who perform pacemaker operations. In the Philadelphia area it is estimated that about 30 sales representatives vie for the attention of about 44 key doctors. Nationwide, analysts estimated that 500 to 550 salespeople are selling to roughly 1,500 physicians.

Not surprisingly, some salespeople go to ambitious lengths to impress potential physician-clients.

"I've known guys to send customized singing telegrams to a prestigious physician in a room full of people — just to get his attention. Hell, I've done that myself," said Leonard Marsharch, a Philadelphia-area salesman. "I've also known guys to give the doctor a flat tire and then be around when he comes out to help him change it. That's a pretty good one."

Physicians were not the only ones treated like sultans. Executives at pacemaker companies reported that some doctors have enjoyed such rewards as vacations, gifts and options to purchase stock at attractive rates from privately held pacemaker companies like Pacesetter Systems.

The physicians also might be treated to lavish dinners and entertainment at the expense of the pacemaker manufacturers. They also may be given private aircraft rides to the company headquarters, where they can learn about technical advances — and where salesmen can improve what they call "client relations."

Then there are the parties at cardiologists' conventions. Javish festivities that in recent years have grown as extravagant — one memorable pacemaker party was held aboard the Queen Mary, another featured band leader Doc Severinsen — that the American College of Cardiology and, the American Heart Association last year attempted to limit the amounts of money that pacemaker companies could spend on entertaining at medical conventions. The medical associations also urged the pacemaker companies to refrain from convention celebrations until 9 p.m. after each day's scientific meetings had concluded.

"We didn't want a mass exodus of doctors leaving to attend a pacemaker function," said Don Jablonski, associate executive director of the American College of Cardiology.

But at the college of cardiology's San Francisco convention last month, it appeared that little had changed.

(Continued on next page)

. . . wine, dine and operate with the people they're trying to sell

Continued from preceding page

Beginning each night at the requisite 9 o'clock, most of the major pacemaker companies — Medtronic, Cordis, Intermedics, Cardiac Pacemakers and Pacesetter Systems — secured dinner reservations for doctors and salesmen at some of the city's leading restaurants and hosted sumptuous cocktail buffets at major hotels.

At the parties, the cardiologists dressed in wall-to-wall to sample free liquor, gourmet food and exotic desserts — served, at one event, by a bevy of waitresses in low-cut outfits.

Said Jablonski: "I'd rather think guys like pacemaker companies would just go away."

But that is a suggestion the industry could ill afford. In recent years, profits at many of the firms have ballooned at rates that have endeared the companies to many Wall Street analysts. Recently, two companies in particular — Intermedics and Pacesetter Systems — have outpaced their competitors.

Sales for Pacesetter, founded in 1970, tripled last year to about $35 million, largely on the strength of its line of Programatith multi-programmable pacemakers. In the first quarter of this year, sales are double the pace of the same quarter last year.

Intermedics, based in Freeport, Texas, closed last year with pre-tax profits of $10.7 million on sales of $105 million, a 35 percent earnings increase over the previous year. In the last five years, revenues and earnings at Intermedics have grown at an annual compound rate of 30 percent, according to the company. Revenues were up 66.2 percent during the first quarter of this year compared with the same period last year.

On March 16, Intermedics received Food and Drug Administration approval for commercial distribution of its CyberLith IV A-V, the first multi-program mobile pacemaker to stimulate both the upper and lower chambers of the heart. The company, founded in 1973 by a former Medtronic salesman, Albert Hestel, introduced the first multi-programmable pacemaker and the first pacemaker that could be monitored by radio (Continued on next page)

(Continued from page 15-A)

frequency.

Intermedics, however, traces much of its recent success to its highly paid independent sales representatives — nearly all of whom, the company said, were pirated from competitors.

In fact, luring established salesmen away from the competition is perhaps the most widely used ploy for gaining market position in the pacemaker industry.

A sales representative who has matured a personal relationship with a number of doctors is almost assured of money-making opportunities. One tactic sometimes used by companies is to increase the price of the pacemaker significantly and offer the difference between the old and new price to the salesman, according to a report issued by the New York investment house of Kidder, Peabody & Co.

In January 1980, Mr. Greible's Delaware Valley sales force was decimated when Pacesetter hired away four of its six salesmen. McGovern, one of those who left Medtronic for Pacesetter Systems at the time, is honest about his reasons. "The money," he said. "I did it for money."

APPENDIX B

SARASOTA, FLA.
SEPT. 14, 1981

SENATOR LAWTON CHILES.
WASHINGTON, D.C.

DEAR SENATOR:

YOU MAY NOT BE THE ONE TO HANDLE THIS PROBLEM, IF NOT YOU WILL KNOW WHO TO GIVE IT TO. WE HAVE HEARD A GREAT DEAL ABOUT THE WORRIES OF MEDICARE, AND MY PROBLEM RELATES TO IT.

. IN 1979 I HAD A PACEMAKER TRANSPLANT AT THE SARASOTA HOSPITAL, DONE BY DR.R.W. HOEFER AND THE PACEMAKER FURNISHED BY THE "INTERMEDICS INC.," OF FREEPORT, TEXAS, AND GUARANTED FOR TEN YEARS. THIS SPRING I WAS NOTIFIED BY THE DR.THAT THE MODEL I HAD WAS GIVING TROUBLE AND THE COMPANY CALLED ALL IN, AT THEIR EXPENSE, AND WE WERE GIVEN SIX MONTHS TO HAVE THEM REPLACED. THE DR. EXAMINED ALL HE HAD IPLANTED, HOW MANY I COULDN'T FIND OUT. HE TOOK THOES NOT WORKING PROPERLY FIRST , AND I WAS ONE OF THEM, AND I WAS AGAIN ASSURED " AT NO COST TO ME".

THE COMPANY, "INTERMEDICS" SENT ME A CHECK IN THE AMOUNT OF $450. TO COVER EXPENSES NOT COVERED BY ME INSURANCE, KNOWING BY MY AGE OF 88YRS IT WAS MEDICARE WHO WOULD BE BILLED: MY HOSPITAL BILL WAS $5426.50, AND THE PACKMAKER ALONE WAS $1900, THE DR'S BILL WAS $505 AND SEVERAL LAB BILLS. OF COURSE THE HOSPITAL BILL WAS PAID BY MEDICARE AND BLUE SHIELD.

HOW MANY HUNDREDS OF THESE WERE CALLED IN OVER THE COUNTRY AND HOW MANY THOUSANDS DOLLARS SPENT BY MEDICARE? ITS ONE OF THE WAYS MEDICARE IS BEING ALKED AND I AM INCENSED OVER IT. WHEN A CAR IS CALLED IN THERE IS NO EXPENSE TO THE CUSTOMER, WHY THIS? EVERY TIME ONE GOES TO THE DR. HIS CHARGE HAS RAISED AND THIS LAST TIME A CHARGE JUST FOR ADMITTING ME TO THE HOSPITAL AND WRITING THE ORDERS, WAS $90. MEDICARE ALLOWED $75.

Please refer this letter to the proper ones.

VERY TRULY YOURS.
(MRS. LOUIS) MADELINE GARMAN.
926 WHITFIELD AVE.
SARASOTA, FLA. 33580

APPENDIX C

50 DIAGNOSTIC SERVICES

50-1 CARDIAC PACEMAKER EVALUATION SERVICES

A. Electronic Pacemaker Analysis Rendered by a Pacemaker Clinic.—Physicians' services and services rendered by others incident to a physician's service by a pacemaker clinic have been shown to be effective in detecting subclinical pacemaker failure and are therefore covered under Part B. The evaluation package of this type of clinic includes EKG and chest x-ray in addition to the electronic analysis of the firing rate and of the amplitude, duration, and shape of pacemaker impulse.

Reasonable utilization parameters have been determined to be three evaluations within the first 12-month period following pacemaker implantation, three evaluations within the next 6 months, and four evaluations within each 6-month period thereafter.

If the pacemaker function is also being monitored by telephone (see B. below), coverage of clinic visits would be at the rate of three visits during the 12-month period following implantation and four visits during succeeding 12-month periods until replacement is indicated. These limits apply when simultaneous utilization begins no matter which service was previously utilized.

Where these parameters are exceeded, documentation of the special circumstances requiring additional visits should be required.

B. Transtelephonic Monitoring of Cardiac Pacemakers.—These services are covered under Part B. Outpatient hospital costs incurred in connection with telephone monitoring of pacemakers are covered under § 1861(s)(2) of the law.

Telephone monitoring of cardiac pacemakers is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement. All systems which monitor the pacemaker spike are effective in detecting subclinical pacemaker failure due to battery depletion. In addition, more sophisticated systems are capable of detecting internal electronic problems within the pulse generator itself, as well as evidence of other potential problems in addition to battery depletion.

There are two major types of pacemaker power sources in current use—the mercury-zinc (HgZn) battery and the lithium (Li) battery. The differences in battery life between the two (lithium batteries generally last considerably longer than mercury-zinc) result in differing monitoring patterns over the expected life of the batteries. Monitoring patterns and frequencies are primarily the responsibility of the patient's physician, taking into account the condition and circumstances of the individual patient. It is possible, however, to develop guidelines within which the vast majority of pacemaker monitorings will generally fall, thus permitting contractors to limit extensive claims development to those cases requiring special attention.

The guidelines below constitute a system which contractors may use, in conjunction with their knowledge of local medical practices, to screen claims for transtelephonic monitoring prior to payment. They are not recommendations with respect to minimum frequency for such monitorings, but rather a maximum frequency for which payment may be made

without further claims development. As with previous guidelines, more frequent monitorings may be covered in cases where contractors are satisfied that such monitorings are medically necessary; e.g., the condition of the patient, or pacemakers exhibiting unexpected defects or premature failure. Contractors should seek written justification for more frequent monitorings from the patient's physician and/or any monitoring service involved.

The guidelines differentiate between mercury-zinc and lithium battery powered pacemakers, and further differentiate between cases in which both a pacemaker and lead have been implanted, and those in which only the pacemaker has been implanted (i.e., the pacemaker was replaced, but the lead was not).

Those guidelines represent, in the case of lithium battery powered pacemakers, an interim recommendation with respect to frequency, which will be reviewed and possibly revised as more data become available. Evidence indicates that some patients may properly be monitored every 8, as opposed to every 4 weeks, but that additional data would be required to be certain.

The guidelines for mercury-zinc (HgZn) and lithium (Li) battery-powered pacemaker telephone monitoring are as follows:

1. Mercury-zinc battery powered pacemakers:

   a. Both pacemaker and lead implanted:

      1st month - once per week
      2nd through 15th month - once every 4 weeks
      16th through 18th month - every 2 weeks
      19th month through to failure - once per week

   b. Only pacemaker implanted, lead not changed:

      1st 2 weeks - once per week
      3rd week through 15th month - once every 4 weeks
      16th through 18th month - every 2 weeks
      19th month through to failure - once per week

2. Lithium battery powered pacemakers:

   a. Both pacemaker and lead implanted:

      1st month - once per week
      2nd month through to failure - once every 4 weeks

b. Only pacemaker implanted, lead not changed:

1st 2 weeks - once per week
3rd week through to failure - once every 4 weeks

It should be noted that the transmitting device furnished to the patient is simply one component of the diagnostic system and a separate charge for it will not be recognized under the durable medical equipment benefit.

Services involving use of telephonic monitoring equipment by a physician or by his office staff under his supervision would be covered under section 1861 (s) (1) or (2) of the law.

Telephonic monitoring services furnished by a supplier are covered under section 1861(s)(3) of the law. The supplier's charge must represent the total charge for all aspects of the monitoring service. The transmitting device furnished to the patient is simply one component of the diagnostic system used in furnishing the service, and a separate charge for its use by the patient will not be recognized under the durable medical equipment benefit. Also, where the supplier's service includes the monitoring of the patient's pulse, and an interpretation and report by a cardiologist is included, the supplier's charge must cover the complete monitoring service including the services of such physician. The statement of the prescribing physician is basic documentation of the validity of the claim. His signed statement should accompany the HCFA-1490 verifying that he received the information as ordered and at the appropriate time.

C. Self-Contained Pacemaker Monitors.--The home use of a self-contained pacemaker monitor is covered under the durable medical equipment benefit since, unlike the transmitting component of a transtelephonic monitoring system, its effectiveness in identifying a change in the patient's pacemaker pulse rate is notdependent upon use of other components located elsewhere. (See § 60-7). Where this method of pacemaker monitoring is employed, the need for periodic checks in the outpatient department of the provider is minimized. Therefore, documentation of the medical necessity for the pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

Cross-refer: HIM 13-3, §§ 3112.3, 3113, §60-9, HIM 14-3, §§ 2060, 2100ff, 2130;

50-2 CYTOTOXIC FOOD TESTS

These are in vitro laboratory tests performed on a venous blood sample which will generally indicate whether the patient has circulation antibodies against the specific food extract tested. Although not appropriate as the sole tool in diagnosing food allergy, cytotoxic food tests are useful as an adjunct to in vivo clinical allergy tests in complex allergy problems. Therefore, program reimbursement may be made for these tests.

Cross-refer: HIM-14-3, §2070

PACEMAKER RECALLS (1972-1982)

Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
T-010-2 (I)	4-1-72	4-10-72	G.E. Stanby Pacemaker*	General Electric Company Milwaukee, WI	Accelerated pace rate due to malfunction of electronic circuitry
T-003-4 (II)	6-29-73	7-17-73	Inhibited Demand Pacemaker Model IDP-44*	Biotronik GMPH and Company Berlin, Germany	Premature failure preceded by an accelerated frequency of pulse generation
T-063-4 (I)	6-8-74	7-10-74	Asynchronous Pacemaker Model A2073*	General Electric Company Milwaukee, WI	Excessive pacing rates - malfunctions of electronic circuitry
T-119/122-5 (II)	10/73 to 3/74	10-23-74	Pacemaker Models Omni-Stanicor 162C; Omni-Ectocor 163A; Omni-Atricor 164; Omni-Ventricor 167A*	Cordis Corporation Miami, FL	Moisture penetration in microcircuitry causing premature battery depletion and pacer failures
T-133/137-5 (I)	10-17-74	11-20-74	Demand Pacemakers Models IRP-44 & IDP-44; Fixed Rate Pacemakers Models IP-44 & IP-45; P-Wave Triggered Pacemaker Model IVP-54*	Biotronik GMPH and Company Berlin, Germany	Excessive premature failure rate - moisture penetration causing premature battery depletion
T-154/157-5 (I)	7/73	1-29-75	Discrete Non-Programmable Pacemakers Models 143 Stanicor; 144 Ectocor; 145 Atricor; and 111 and 154 Ventricor*	Cordis Corporation Miami, FL	Pacer failures due to moisture and other contamination of electronic components
T-159/161-5 (I)	6/74	2-5-75	Vitatron Pacemakers Models MIP-40; MIP-41; MIP-501*	Vitatron Medical Dieven, Holland	Premature pacer failures due to bat: electrolyte leakage into electronic circuitry
T-163-5 (II)	12-16-74	2-26-75	Stanicor Discrete Pacemaker Model 1435/4N7*	Cordis Corporation Miami, FL	Decreased pacer rate - malfunctions attributed to defective transistor
T-191-5 (I)	4-21-75	5-27-75	Myocardial Lead for Rechargeable Pacemaker Models BL-652 & BL-653*	Pacesetter Systems, Inc. Sylmar, CA	Loss of electrical continuity due to fracture of central diameter wire for electrode tip
T-197/198-5 (I)	4-30-75	5-21-75	Vitatron Pacemaker Models MIP-151P and MIP-251P*	Vitatron Medical Dieven, Holland	Premature pacer failures due to battery electrolyte leakage into electronic circuitry

(Class)	Date	nouncement	(& Distribution Inf), & Quantity	Manufacturer	Reason
T-200-5 (II)	5-27-75	6-4-75	Sentry 75 Pacemaker*	General Electric Company Milwaukee, WI	Premature battery depletion causing decrease in pacer rate - body fluid penetration into battery area
T-210-5 (II)	4-10, 6-6, & 6-9-75	7-9-75	Xytron Pulse Generator Model 5950*	Medtronic, Inc. Minneapolis, MN	Three units distributed containing defective transistor components
T-211-5 (II)	7-3-75	7-9-75	American Optical Model 262002*	American Optical Corporation Bedford, MA	Excessive pacing rates than indicated by control rate dial at high pulse rate settings
T-045/048-6 (II)	12-18-75	1-14-76	Xytron Pulse Generators Models 5950, 5951, 5912 and 5913*	Medtronic, Inc. Minneapolis, MN	Electrical leakage resulting in premature battery depletion and pacer failures
T-098-6 (II)	2-4-76	5-5-76	Demand Pacemaker Model MOS-1*	Intermedics, Inc. Freeport, TX	Premature battery depletion and pacer failure due to contamination and fluid buildup around feed-through area of electronic circuitry
T-111/112-6 (II)	5-26-76	6-23-76	Kappa R-Wave Cardiac Pacers Stanicor Model 171; Ectocor® Model 172*	Cordis Corporation Miami, FL	Defective weld seals resulting in penetration of body fluids causing electronic circuitry corrosion and pacer failures
T-117/118-6 (II)	5-21-76	7-14-76	Starr Edwards Pacemakers Models 8131 and 8116*	Edwards Pacemaker Systems Irvine, CA	Corrision of output pin causing pacer failures due to fluid penetration through epoxy barrier
T-120/121-6 (II)	4-21-76	7-21-76	Bielectrode Pacing Kit and Various Pacing Probes*	Electro-Catheter Corporation Rahway, NJ	Structural defect causing leads attached to pulse generator to become disconnected from pacing probe conduit, resulting in an interruption of the connection with external pulse generator
T-129/132-6 (II)	7-12-76	8-4-76	Vitatron Pacemakers Models 40RT, 41RT, 501T and 501TC*	Vitatron Medical Dieven, Holland	Gradual increase of pacer base stimulation rate due to corrosion of frequency resistor component
T-133-6 (II)	7-7-76	8-4-76	Plastron DL Ventricular Demand Pacers Model 4800 (Stim. Tech No. 7017)*	Devices, Ltd. Hertfordshire, England	Faulty welding of wires internal to the pacemakers
T-138/139-6 (II)	8-2-76	8-25-76	Xytron Pacemakers Models 5950 and 5951*	Medtronic, Inc. Minneapolis, MN	Permeation of water vapor through seal to electronic circuitry resulting in sudden cessation of pacer output

Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
T-144-6 (II)	7-22-76	9-8-76	Pulse Generator Connector, Catalog No. CA-276*	Electro-Catheter Corporation Rahway, NJ	Structural defect causing leads attached to pulse generator to become disconnected from pacing probe conduit, resulting in an interruption of the connection with external pulse generator
T-018-7 (II)	11-22-76	12-8-76	Xytron Pacemaker Model 5912*	Medtronic, Inc. Minneapolis, MN	Permeation of water vapor through seal to electronic circuitry resulting in sudden cessation of pacer output
T-060-7 (II)	2-2-77	2-23-77	ESB Medcor Demand Pacemaker Model 3-70B*	Medcor, Inc. Hollywood, FL	Defective transistor component resulting in erratic pulse rate generation and cessation of output
T-069/072-7 (II)	2-19-77	3-23-77	Micro 7 Models DU700 & DB800; Micro 12 Models DU300; DU301; DB400; DB401 pacers*	American Technology, Inc. Northridge, CA	Defective capacitors contained in pacers resulted in decreased pulse rates and complete cessation of pulse generation
T-074-7 (II)	3-10-77	3-30-77	Interlith Lithium Pacemaker Model 223C-MOS-1*	Intermedics, Inc. Freeport, TX	Pacers produced abnormal pulse following normal timed pulse - defective design of electronic circuitry
T-075/076-7 (II)	3-1-77	3-30-77	Vitatron Pacemakers Models 40RT and 41RT*	Vitatron Medical Dieven, Holland	Reduced pulse rate and premature battery failure due to migration of mercury to zinc and resulting in battery short circuit
T-121-7 (II)	6-2-77	6-22-77	R-Wave Demand Mercury Powered Pacemaker Model 3821 Series*	Stimulation Technology, Inc. Minneapolis, MN	Cessation of output due to fluid penetration and metal plating across an electrical terminal
T-129-7 (II)	6-8-77	7-13-77	Models 8204, 8206, 8208 Pacemaker Endocardial Leads with "Elgiloy" connector pins*	Edwards Pacemaker Systems Irvine, CA	Defective connecting pins which may result in failure in pacemaker to conduct cardiac pulse generation
T-137/138-7 (II)	6-28-77	8-10-77	Edwards Pacemakers Models 8114 and 8116*	Edwards Pacemaker Systems Irvine, CA	Premature battery depletion causing decreased pulse rate and ultimate cessation of pacing
T-208-7 (II)	9-27-77	10-12-77	R-Wave Demand Pacemakers Model 3821 Series, all production*	Stimulation Technology, Inc. Minneapolis, MN	Variable pulse rate deviations - defective electronic capacitor component

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Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
T-022/024-8 (II)	10-26-77	11-23-77	Xytron Pacemakers Models 5913, 5954 and 5955 (1100)	Medtronic, Inc. Minneapolis, MN	Permeation of water vapor through seal to electronic circuitry resulting in sudden cessation of pacer output
T-037-8 (II)	11-4-77	12-21-77	Hewlett-Packard External Pacemaker Model 7834A (75)	Hewlett-Packard Company Waltham, MA	Cessation of pulse generation due to moisture penetration of encapsulant material
T-059-8 (III)	1-22-78	3-8-78	ECG Transmitter Monitor Model 193B (not a pacemaker) (11)	Norland Corporation Fort Atkinson, WI	Faulty reverse installation of diodes resulting in failure to show capture of pacer spikes in small percentage of patients
T-103/105-8 (II)	4-17-78	5-31-78	Lithium Powered Pacemakers Models Li2F and 2Ds Li-3D, and Li-4D (269)	ARCO Medical Products Leechburg, PA	Premature failure due to short circuit - metallic dendridic growth across insulator gap of feed-through circuitry
T-334/335-8 (II)	8-21-78	9-13-78	Microlith-P Models 0505, 0605 (738)	Cardiac Pacemakers, Inc. St. Paul, MN	Defective quartz crystal
T-030-9 (II)	11-27-78	1-17-79	Unipolar Demand Pacer, Model DU300 (28)	American Technology, Inc. Northridge, CA	Contains possibly defective lithium batteries manufactured by Catalyst Research Corporation
T-031-9 (II)	12-14-78	1-17-79	Li-Iodine BP Cardiac Pacer Model UDL-100 (8)	Pacesetter Systems Sylmar, CA	Contains possibly defective lithium batteries manufactured by Catalyst Research Corporation
T-032-9 (II)	12-5-78	1-17-79	Li-Cardiac Pacer, Model 1600 (2)	American Pacemaker Corporation Woburn, MA	Contains possibly defective lithium batteries manufactured by Catalyst Research Corporation
T-033-9 (II)	11-21-78	1-17-79	AB QRS Inhibited Lithium Pacer Models 207 and 217 (8)	Elema-Schonader, Inc. Elk Grove Village, IL	Contains possibly defective lithium batteries manufactured by Catalyst Research Corporation
T-034-9 (II)	12-8-78	1-17-79	Pulse Generator Pacemakers Model 223 (113)	Intermedics, Inc. Freeport, TX	Contains possibly defective lithium batteries manufactured by Catalyst Research Corporation

Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
T-282/283-9 (II)	6-20-79	6-27-79	Models 1611 and 1613 Implantable Lithium Unipolar/Bipolar Demand Pacemakers (553)	American Pacemaker Corp. Woburn, MA	Variable pulse rate deviation - defective transistors
T-304/307-9 (II)	8-10-79	8-29-79	Micro 7 and Micro 12 Pacers Models DU700/800, DB301/401 (1300)	American Technology, Inc. Northridge, CA	Excessive premature failure rate
T-033-0 (I)	12-20-79	1-9-80	Unipolar Demand Pacemaker Model DU33 (250)	American Technology, Inc. Northridge, CA	Interruption of sensing and possible short circuit and immediate cessation of pacing due to dendritic growth by migration of metals attributed to moisture penetration and internal contamination.
T-080-0 (I)	5-5-80	6-25-80	Temptron 6705 and 6705A Temporary Pacing Lead (655)	Medtronic, Inc. Minneapolis, MN	Lead erroneously packaged with incorrect diameter size of lead introducer too small to allow lead to pass through into the vein for eventual placement into the heart.
T-170-0 (I)	8-8-80 10-31-80	11-26-80	L-500 Pacemaker (2500)	Coratomic, Inc. Indiana, PA	Premature battery depletion resulting in premature pacer failure including abrupt loss of input.
Pacemaker Advisory	Unclassified 3-12-80 8-3-80		XYTRON II Pacemaker	Medtronic, Inc. Minneapolis, MN	Notice of Performance Experience Data (premature failure rates and no output modes)
Pacemaker Advisory	Unclassified 8-21-80		Minilith and Maxilith Pacemakers	Cardiac Pacemakers, Inc. Minneapolis, MN	Notice of Performance Experience including incidents of no output and runaway pacers.

Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
Pacemaker Advisory	Issued by FDA 9/18/80		All models of pacemakers manufactured	American Technology, Inc. Northridge, CA	Notification of available adverse implant experience information and recommendations to physicians indicated following firm's termination of operation.
T-064-1 (II)	12/19/80	1/28/81	Medcor Lithicron Implantable Unipolar Pulse Generator R-Inhibited Type VVI, Model 0311 (10)	Medcor, Inc. Hollywood, FL (Recaller: Diag Corp. Minnetonka, MN)	Non-Sterility
Pacemaker Advisory	Unclassified 2/23/81		Medcor Lithicron Multiple Unipolar Pulse Generator, Model 0511	Daig Corp. Minnetonka, MN	Notification of myopotential inhibition in uncoated pulse generators and recommendations to physicians to adequately monitor pacer dependent patients.
T-005/ 007-2 (1)	3/28/81	11/11/81	ARCO Pulse Generators, Models Li-3, ARCOlith-3 and ARCOlith-4 (5055)	Intermedics, Inc. Freeport, TX	Premature battery depletion without adequate end-of-life indications.
Pacemaker Advisory	Unclassified 10/23/81		CyberLith IV Model 2509-01 AV Sequential Pulse Generator (3698)	Intermedics. Inc. Freeport, T.	CRC 800 Series batteries do not meet projected longevity.
T-132/ 133-2 (II)	1/21/81	4/14/82	Microthin Pulse Generators Unipolar Models 0520, 0521, 0522, 0523, and Bipolar Models 0620, 0621, 0622 and 0623	Cardiac Pacemaker, Inc. St. Paul, MN	Some set screws packed with devices may be too short to make contact with the lead terminal pin in the connector block, resulting in failure to complete electrical circuit.

Recall No. (Class)	Recall Date	FDA Announcement	Product & Approximate Amount of Distribution (No. of Units)	Manufacturer	Reason
T-138-2 (II)	2/5/82	5/5/82	Quantum Pulse Generators, Model 253-09, 254-09, 254-10 (86)	Intermedics, Inc. Freeport, TX	Some pacers programmed for the maximum 120 ppm rate and programmed at the maximum pulse width and pulse amplitude may revert to 70/72 ppm.
T-140/ 141-2 (II)	3/10/82	5/12/82	SX-HT High Threshold Pacemakers, Multi-Programmable Models 5976 Bipolar and Model 5977 Unipolar (427)	Medtronic, Inc. Minneapolis, MN	Units have the potential for exhibiting undersensing or no sensing under specific conditions.

*Distribution records on individual recalls prior to 1978 have been transferred to FDA Agency Records Section Archieves and are not immediately available.

APPENDIX E

Since the Medical Device Amendments became effective on May 28, 1976, the following Premarket Approval Applications have been received by the Division of Cardiovascular Devices:

- Concept, Inc. (formerly Barlow Manufacturing Co.), Hunter-Sessions Vena-Cava Occluder, approved December 19, 1977 - a catheter with a detachable balloon, which is inserted in the right jugular vein and passed through the inferior vena cava to a position between the iliac vein and the renal veins. The balloon is inflated with a radiopaque solution, and disengaged from the catheter, in order to occlude the vessel and prevent the migration of venous thromboemboli. The device is indicated for certain patients with inferior vena cava thrombus.

- Meadox Medicals, Inc., Dardik Biograft, approved January 15, 1979, amended May 8, 1981 to include a new rinse procedure during its manufacture and its irrigation procedure before being implanted - a human umbilical cord vein, surrounded by a Dacron polyster mesh, used to replace sections of occluded peripheral arteries in the legs.

- Shiley, Inc., Bjork-Shiley Prosthetic Heart Valve with Convexo-Concave Occluder, approved April 27, 1979 - a mechanical, pivoting disc cardiac valve recommended for the replacement of malfunctioning aortic, mitral or tricuspid heart valves.

- Medtronic, Inc., Byrel^{R} Model 5992 Programmable A-V Sequential Pacemaker, approved March 27, 1979, amended July 21, 1981 to change the power source - an implantable atrio-ventricular pacemaker programmed with eight different pacing modes, seven for A-V pacing and one for ventricular sensing, ventricular stimulating, inhibited pacing.

- Becton Dickinson and Company, Mini-Balloon Detachable Balloon Catheter System, approved August 17, 1979, amended November 27, 1981 to include use of 1 and 2 mm system for arterio-venous malformations and use of the 2mm system for previously approved 1 mm system applications - a catheter with a detachable balloon intended for the permanent occlusion of arteries up to four mm in diameter when applied in non-surgical control of hemorrhage and when used pre-operatively to reduce blood loss during removal of vascular tumors.

- Vascor, Inc. (formerly Hancock Laboratories, Inc.), Model 250 Modified Orifice Aortic Bioprosthesis and Model 150 Modified Orifice Valved Conduits, approved November 15, 1979 - the Model 250 is a composite porcine valve indicated

for the replacement of diseased human aortic valves; the Model 150 is a composite porcine valve which is sutured into a Dacron graft prosthesis for the replacement of major vessels primarily in children with congenital malformations.

- C.R. Bard, Inc., USCI® Gruntzing Dilaca™ Coronary Artery Balloon Dilatation Catheter, approved March 24, 1980, amended February 17, 1981 to use Cobalt 60 sterilization, amended September 30, 1981 to change the material for the balloon marker bands and to use dosimetric release in lieu of the classic sterility test - a double lumen catheter whose balloon is designed to be inflated to a known diameter and length for use in dilatation of stenoses in coronary arteries in patients with single or multiple coronary vessel disease.

- Intermedics, Inc., CyberLith™ IV Model 259-01 Programmable A-V Sequential Pulse Generator and Series 522 Programmer, approved August 18, 1980, amended June 12, 1981, to include the use of a different battery - the Model 259-01 is an implantable pacemaker programmed for operation in any of three modes: demand ventricular inhibited, A-V sequential fixed-rate, and A-V sequential demand; the Series 522 Programmer is a rechargeable, battery operated electronic device which generates and transmits data to program the pacemaker and initiates transmission of telemetry data.

- Interface Biomedical Laboratories, Inc., N.C.G.T™ Graft, approved September 8, 1981 - a bovine carotid or brachial artery of six millimeters or greater diameter, intended for use as a peripheral vascular replacement where bypass or reconstructive surgery is indicated in arterial disease. Not approved for use in coronary bypass surgery or as an arterio-venous shunt.

- Medtronic, Inc., The Hall-Kaster Prosthetic Heart Valve Models A7700 and M7700, approved December 23, 1981 - a mechanical, pivoting disc, cardiac valve recommended for the replacement of malfunctioning aortic, mitral or tricuspid heart valves.

- St. Jude Medical, Inc., Bi-Leaflet Prosthetic Heart Valve, recommended for approval on October 23, 1981 - a mechanical bi-leaflet cardiac valve recommended for the replacement of malfunctioning aortic, mitral or tricuspid heart valves.

- Siemens Corporation, Siemens-Elema Endocardial Carbon Tipped Leads - Models 411S(flanged) and 412S(tined), recommended for approval on October 23, 1981 - a permanent pacemaker electrode indicated for use where a permanent implantable pacemaker is required. These leads are distinguished from other leads presently in use by their activated vitreous carbon tips.

- Advanced Catheter Systems, Inc., Simpson-Robert™ Coronary Balloon Dilatation Catheter, recommended for approval on October 23, 1981 - a double lumen catheter with an inflatable balloon used for dilatation of stenoses in coronary arteries in patients with ischemic heart disease and angina pectoris who have failed medical therapy and have therefore become candidates for cornary bypass graft surgery.

- Extracorporeal, Inc., (Johnson and Johnson Company, formerly Surgikos, a Johnson and Johnson Company), Surgikos Artegraft and Surgikos Reinforced Artegraft, approved-August 1, 1979, (initially approved by Bureau of Drugs on January 26, 1970), amended May 4, 1981 to change storage time of raw material - a bovine carotid artery intended for use distal to the aorta as a segmental arterial replacement, or arterial bypass, or arterio-venous shunt, or patch graft. Not approved for use in coronery bypass surgery.

APPENDIX F

PRESS RELEASE

The first in a series of Advanced Function Pacemakers (AFP), manufactured by Pacesetter Systems Inc.. of Sylmar, California, was implanted in a 70 year old recipient by Dr. John Messenger and Dr. Mark Castellanet at Memorial Hospital Medical Center of Long Beach, in California.

The implant took place on Monday, March 1, 1982, and represents a major milestone in the advancement of pacemaker therapy. This new device is designed to pace the patients' heart more physiologically than with current pacemaker therapy by automatically adjusting the patient's rate to actual needs.

This new pacemaker incorporates a radio transmitter that telemeters the patients electrocardiogram, as well as diagnostic data, to a computer console that displays the information on a television style screen to help the physician in his diagnosis and patient care.

We congratulate the superb team of engineers and physicians who participated in the development of this extraordinary new generation of cardiac pacemaker.

Pacesetter Systems, Inc.
12884 Bradley Avenue, Sylmar, California 91342 U.S.A. (213) 362-6822, (800) 423-5611 Telex: 698415

APPENDIX G

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE April 5, 1982
FROM: Glenn A. Schmaltz HFK-450 A.F.		OFFICE 443-680 File
TO: Harry Butts (HFK-110); Wiley T. Lam		DIVISION , Ph.D. (HFK-142)
SUBJECT: Pacesetter Systems, Inc.; Press Release		

SUMMARY

Last week I sent you a memo regarding an advertisement which appeared in the Journal of Thoracic and Cardiovascular Surgery. Pacesetter advertised its Advanced Function Pacemaker (AFP) for which it does not have either marketing approval or IDE approval.

I also read a story in the Heavy Chest about an IDE which Pacesetter has submitted to FDA for their AFP pacemaker & we are recommending that the IDE be denied at this time because the qualification testing of the integrated circuits has just begun and will not be completed for several months. The Heavy Chest story was based on a press release from Pacesetter.

I have attached a copy of the Pacesetter press release which I just received. This appears to me to be premature by the company since nowhere do they mention that this is not yet available for clinical investigation. The company also appears to be making a claim of safety and effectiveness for this device when they state in the press release that it "represents a major milestone in the advancement of pacemaker ~~technology~~."

I believe that Pacesetter Systems, Inc. is promoting this device and, based on the large number of emergency uses of their investigational DVI pacemaker (between 100 and 200), is doing so for the purpose of making the AFP available to

SIGNATURE physicians as an emergency use device.	DOCUMENT NUMBER
Glenn A. Schmaltz	

FORM FD 2024 (6/76)

Telephone MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE April 5, 1972
Between: FROM: Alfred Mann (Pacesetter Systems, Inc.)		OFFICE
and: TO: Glenn Rahmoeller (HFK-450)		DIVISION A.F. 42-680 FILE

SUBJECT: Pacesetter's Premarket Approval Application (PMA).

SUMMARY P810064, ~~from~~ for the Programmable AV (PAV) pulse generator and programmer.

Mr Mann called me today to ask for my help regarding this PMA. He noted that it was submitted to FDA (letter dated march 26, 1982 - received by Document Control on march 30, 1982) but that Jim Moore has asked that it be withdrawn because of some omissions in the PMA. Mr Mann said that the company must have the PMA revised by FDA's advisory panel at its may 14 meeting. He asked whether he should withdraw the PMA and resubmit it (probably by next monday) or whether he should leave it with FDA to review while the ~~supplements~~ amendments are being prepared.

I said that it would be best if the PMA is as clean as possible, but that we may not be able to review it at our may meeting. I noted that if the PMA is submitted with the revisions next monday we will have less than five weeks to review it and send it to the Panel.

In response, Mr. Mann said that if FDA does not review this PMA at its may 14 meeting, Pacesetter may have no choice but to market the device without approval.

I said that if Pacesetter does market the device without PMA approval, I will recommend regulatory action. I said that I believe that Pacesetter Systems may already be violating the Food, Drug, and Cosmetic Act (Act) by their recent press release

SIGNATURE	DOCUMENT NUMBER
HFK	page 1 of 3

FORM FD 2034 (6/76)

Telephone MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 4/5/82
Person FROM: Alfred Mann (Pacesetter)		OFFICE
And TO: Glenn Rahmoeller (HFR-450)		DIVISION
SUBJECT: PMA 810064 - PAV pacemaker and programmer		

SUMMARY

for this advanced function pacemaker (AFP). A said that A ~~would~~ consider such a release to be premature. (This device does not yet have either approval for marketing or an investigational device exemption (IDE)). (Mr. Mann did not know about the release - A read it to him.)

Mr. Mann said that he has tried to comply with FDA. He said that he has been offered help through Dr. Hayes and Orrin Hatch (A suggests people who have influence with Dr. Hayes and Senator Hatch), that he has not sought this help before but may do so.

A said that FDA is required to review a PMA within six months after it is filed. A said that we will do so with this PMA once it is completed and filed, but that it may not be reviewed at the May 19 Panel meeting. A said that we could review it at a subsequent Panel meeting (possibly in July) and still meet the six months deadline.

A noted my concern about Mr. Mann's statements about possibly marketing the PAV without PMA approval. A also referenced previous statements by Mr. James Moore at a UCLA medical device workshop last summer when he said that the welfare of the company comes first, then the patient, and then the physician. At that time Mr. Moore also said that when a physician puts down cash for a pacemaker, even if it is still under investigation, it is hard to turn down.

Mr. Mann said that he will not market this pacemaker without PMA approval unless (a) he feels that

SIGNATURE	DOCUMENT NUMBER
[signature]	Page 273

FORM FD 2034 (6/76)

Title MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 4/5/82
Between: FROM: Alfred Mann (Pacesetter)		OFFICE
And: TO: Glenn Rabenstein (HFK-450)		DIVISION

SUBJECT: PMA P810064

SUMMARY

he has to and (5) his lawyers believe that Pacesetter will win in court.

I again said that if Pacesetter does that, I will recommend regulatory action.

During the conversation, Mr. Mann said that he did not really believe that Pacesetter needed FDA/PMA approval for the PAV, [redacted] but that they have chosen to try to comply with FDA's requirements.

Glenn A. Rabenstein

SIGNATURE	DOCUMENT NUMBER Page 3 of 3

FORM FD 3034 (4/76)

APPENDIX H

July 1-1982.

Dear Sir:-

Enclosed are copies of my bills for the two Pacemakers.

The second time the P.M. only had to be attached to the existing wires into the Heart, consequently the difference in the bills.

If I can be of further help please call.

Thanks for your trouble.

M. Garman

STATEMENT 1st Transplant

C. A. LUER, M.D. 58058
W. L. CHAPMAN, M.D. 58136
J. W. REEDER, M.D. 58186
J. O. FERGESON, M.D. 58074
F. H. PFEIFFENBERGER, M.D. 58142
PROFESSIONAL ASSOCIATION
GENERAL, THORACIC AND CARDIOVASCULAR SURGERY
SUITE 222 • 1950 ARLINGTON STREET
SARASOTA, FLORIDA 33579
TELEPHONE: 366-4282
R. W. HOEFER, M.D., 58240
Surgeon

Madeline Garman
925 Whitfield Av
Sarasota, Fla. 33580

☐ OFFICE ☐ HOSPITAL [illegible] MEDICARE NO.

FOR PROFESSIONAL SERVICES Dr Hoefer

DIAGNOSIS Intermittent heart block

PROCEDURE: DATE 1-3-79 insertion of cardiac pacemaker
33205 $835.00

JAN 3 0 1979

ADM. 12-26-78 DISCH 1-10-79

SURGICAL ASSIST TO DR.

TAX ID #59-1300601

NO DUPLICATE BILLS WILL BE ISSUED
PLEASE RETAIN ONE COPY FOR YOUR FILE

TOTAL $883.00

~~typed from Card~~
Copy - Model #DU-15 } I carry cards
Serial # B-1402 }

STATEMENT

GULF COAST ANESTHESIOLOGY ASSOCIATES

1837 HILLVIEW STREET
SARASOTA, FLORIDA 33579
PHONE 366-5515

Madeline M. Garman
926 Whitfield Ave.
Sarasota, Fla. 33580

Edward A. Ellis, M.D.

NUMBER	DATE	DESCRIPTION	CHARGE	PAYMENT	CURRENT BALANCE
7583	1/5/79	Anesthesia	165.00		165.00

Local anesthesia with IV supplementation for:
#33205-30
~~Time: 6:55-8:00~~
Memorial Hospital

1-30-79
GULF COAST ANESTHESIOLOGY ASSOCIATES

16767
59 1353626

PLEASE PAY LAST AMOUNT IN THIS COLUMN

THIS IS A COPY OF YOUR ACCOUNT AS IT APPEARS ON YOUR LEDGER CARD

STATEMENT

Eugene D. Liddy, M.D.
INTERNAL MEDICINE & CARDIOLOGY
MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET
SARASOTA, FLORIDA 33579

Mrs. Madeline Garman
926 Whitfield Avenue
Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
12/26/78 thru				
12/31/78	Hospital visits	$210.00		
1/3/79 thru				
1/9/79	Hospital visits	$175.00		$385.00

12/26/78 90220 $85.00, 12/27 thru 12/31/78 daily 93277 @ $25.00 per day, 1/3/79 thru 1/9/79 daily 93277 @ $25.00 per day.

Cardiac arrhythmia variable in type. Periods of advanced auriculoventricular block, congestive heart failure.

PAID 1-22-79 E. D. L. M.D.

PLEASE PAY LAST AMO IN THIS COLUM

Hospital stay

STATEMENT

Eugene D. Liddy, M.D.

INTERNAL MEDICINE & CARDIOLOGY

MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET

SARASOTA, FLORIDA 33579

Mrs. Vadeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
4/22/78	Paid		$33.00	00.00
5/30	90060	$20.00	$20.00	
6/29	90060	$20.00		$20.00
7/8	Paid		$20.00	00.00
9/28	thru			
10/9	Hospital visits	$216.00		$216.0
10/27	Paid		$216.00	00.00
12/26/78	thru			
12/31/78	Hospital visits	$210.00		
1/3/79	thru			
1/9/79	Hospital visits	$175.00		$385.0
1/22/79	Paid		$385.00	00.00
3/26	90060	$20.00	$20.00	
8/6	90060	$25.00	$25.00	
8/27	90060	$25.00		
	Flu vacc.	$10.00		$35.0

PLEASE
PAY LAST AM
IN THIS COLU

MEMORIAL HOSPITAL
1901 ARLINGTON ST.
SARASOTA, FL. 33578
A NOT FOR PROFIT HOSPITAL OWNED AND OPERATED BY
THE SARASOTA COUNTY PUBLIC HOSPITAL BOARD

(1) HOSPITAL NO	(2) PROVIDER NO	(4) FED. I.D. NO
10176-1	513	100087	59-60-12560

(3) PATIENT'S LAST NAME | FIRST NAME | INITIAL | (5) STREET ADDRESS | CITY | STATE | ZIP

GORMA M MADELINE | 926 WHITFIELD AVE | SARASOTA | FL | 33580

(6) PATIENT CONTROL NO	(7) BIRTHDATE	(8) ATTENDING PHYSICIAN	(9) ADMISSION START OF CARE DATE	HR	(10) DURATION OF SERVICE STAT DATES FROM	THRU	(11) H.S.
12133 7 21	2 03 1903	LIDDY	12267	11			

(12) PRIMARY PAYOR NAME	(13) INSURED'S NAME & RELATIONSHIP TO PATIENT	(14) CLAIM CERTIFICATE I.D. NO (M.I.C.)	(15) GROUP NAME NO.
MEDICARE		268837222	
(16) SECONDARY PAYOR NAME	(17) INSURED'S NAME & RELATIONSHIP TO PATIENT	(18) CLAIM CERTIFICATE I.D. NO (M.I.C.)	(19) GROUP NAME NO.
BLUE CROSS	PATIENT	268488170	CCC-140
(20) TERTIARY PAYOR NAME	(21) INSURED'S NAME & RELATIONSHIP TO PATIENT	(22) CLAIM CERTIFICATE I.D. NO (M.I.C.)	(23) GROUP NAME NO.

(24) BILL TO: MADELINE GARMAN
26 WHITFIELD AVE
SARASOTA FL 33580

(25) TYPE OF BILL: IP

PROFESSIONAL COMPONENTS: (26) RADIOLOGY (27) PATHOLOGY (28) OTHER

(29) MDNT CUSTDY SUNDRY RATE: 04400 (30)

(31) CODE	(32) DESCRIPTION	(33)	(34) TOTAL CHARGES	(35) PRIMARY PAYOR	(36) SEC. PAYOR ITEM 29	(37) TERT. PAYOR ITEM 25	(38) PATIENT
51	SEMI-PRIVATE 104.00	015	1560 00	1560 00			
02	OPERATING ROOM		231 0	2 100			
05	ANESTHESIA SUPPLIES		12 0	1 200			
06	LAB		179 0	1 450			
08	X-RAY		83 0	1 100			
10	DRUGS-SOLUTIONS		230 35	230 35			
11	STERILE SUPPLIES		732 0	2732 50			
96	CARDIAC PACEMAKER IMPLANT		230 0	2 000			
16	[illegible]		150 00	1 5000			
27	NUCLEAR MEDICINE		22 0	220			
	TOTALS →		5426 5	5426 85			

(39) BLOOD RECORD (PINTS)

(42) PINTS	(43) NOT REPLACED	(44) NOT REPLACED	(45) CHG PER	(46) TREATMENT AUTHORIZATION	(47) INPATIENT DEDUCTIBLE	(48) DEDUCTIBLES	(49) DEDUCTIBLES	(50) DEDUCTIBLES	(51) PAID BY PATIENT
					$ 14600				

(52) STATEMENT COVERS PERIOD FROM 12 07 THRU 01 07 (53) CONDITIONS (54) DAYS (55) RATE (56) L.R. DAYS USED (57) PIP (58) (59) (60) COINSURANCE

(61) OCCURR DATE	(62) CODE	(63) OCCURR DATE	(64) CODE	(65) COV DAYS	(66) CONTR DAYS	(67) COINSURANCE	(68) COINSURANCE	(69) COINSURANCE

AMOUNT DUE

(70) DUE FROM PRIMARY PAYOR	(71) DUE FROM SEC. PAYOR ITEM 29	(72) DUE FROM TERT. PAYOR ITEM 25	(73) DUE FROM PATIENT
5278 35	14600		

ALL SUMS DUE AND PAYABLE UPON DISCHARGE. ALL BALANCES OVER 30 DAYS SUBJECT TO 10% CHARGE.

NOTICE TO PATIENT: THE HOSPITAL IS ACTING SOLELY AS AN AGENT FOR THE PATIENT IN FILING FOR ASSIGNED INSURANCE BENEFITS AND THEREFORE IT CAN ASSUME NO RESPONSIBILITY FOR THE GUARANTEE OF COVERED CHARGES AS SHOWN FOR PRIMARY AND SECONDARY PAYORS. ACTUAL CREDIT WILL BE GIVEN WHEN THE MONEY IS RECEIVED.

SHOULD AN OVERPAYMENT BE MADE, A REFUND CHECK WILL BE SENT TO THE AUTHORIZED PARTY.

UB16 78

SIGNATURE ON HOSPITAL SERVICES ONLY. AUTHORIZE RELEASE OF PHYSICIAN OR PROFESSIONAL CHARGES INCLUDING [illegible]
[illegible] SERVICES FOR WHICH I AM ORDERED BY YOUR PHYSICIAN.

FORM SSA-1533 (1-77)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE / SOCIAL SECURITY ADMINISTRATION

MEDICARE HOSPITAL, EXTENDED CARE AND HOME HEALTH BENEFITS RECORD

J1549031903A552 100087

DATE: 02/16/79

MADELINE GARMAN
926 WHITFIELD AVE
SARASOTA FL 33580

HEALTH INSURANCE CLAIM NUMBER
262-48-8722D

Always use this number when writing about your claim.

THIS IS NOT A BILL. This notice is to give you a record of the Medicare benefits you used during the period shown in Item 1. For important additional information please see the other side of this form.

1 OUR RECORDS SHOW THAT YOU RECEIVED THESE SERVICES

Type of Services	Services Were Provided By	Date
INPATIENT HOSPITAL	MEMORIAL HOSP 1901 ARLINGTON ST SARASOTA FL 33579	12/26/78 THRU 01/10/79

2 MEDICARE HAS PAID FOR ALL COVERED SERVICES EXCEPT

$144.00 FOR THE INPATIENT DEDUCTIBLE.

IF YOU HAVE ANY QUESTIONS ABOUT THIS RECORD PLEASE GET IN TOUCH WITH:

BLUE CROSS OF FLORIDA INC
PO BOX 2711
JACKSONVILLE FLORIDA 32201

3 OUR RECORDS SHOW THE FOLLOWING BENEFITS WERE USED THIS TIME

Inpatient Hospital Days	Lifetime Reserve Days	Extended Care Days	Home Health Visits Hospital Insurance	Home Health Visits Medical Insurance
15				

Blue Cross

P.O. Box 1798
532 Riverside Avenue
Jacksonville, Florida 32231
(904) 354-3331

Date Claim Paid: 02-03-79

Contract Number: 262488670
Patient Name: GARMAN M
Hospital Code: 513
Type Srvc: I
Group Number: 99999
Division Number: SEA
Admission Date: 12-26-78
Check Date:
Hospital Name: MEMORIAL HOSPITAL
Days Approved:

GARMAN MADELINE M
926 WHITFIELD AVE
SARASOTA FLA
33

This statement represents a summary of how your recent hospital charges were processed. On the reverse side you will find an explanation of codes used on this statement.

Claim Number:

Days Paid: 000
Amt Charged: 144
Deductible: 0
Amt Paid: 144.00
Patient Acct No: 1313397
Date Claim Received: 01-31-79
Disposition: PD TO HOSPITAL

DESCRIPTION	CHARGES	PAYMENT
MEDICARE DEDUCTIBLE	144.00	144.00
TOTAL	144.00	144.00

THIS IS NOT A BILL

PLEASE KEEP FOR YOUR RECORDS
DUPLICATES CANNOT BE PROVIDED

RICHARD W. HOEFER, M.D., P.A., F.A.C.S.
General, Thoracic and Cardiovascular Surgery
DOCTORS HOSPITAL MEDICAL COMPLEX, SUITE 303
2650 BAHIA VISTA STREET
SARASOTA, FLORIDA 33579
(813) 957-1168

2nd.

Mrs. Madeline Garman
926 Whitfield Ave.
Sarasota, Fl. 33580

355-3235

NUMBER	DATE	DESCRIPTION	CHARGES	PAYMENT	CURRENT BALANCE
5193	5/5/81	Surgical Consultation req by Dr. Liddy	60	-0-	60
	5/5/81	Hospital Admission	60		60
5217	5/14/81	Pacemaker battery Replacement	150		510
	5/15/81	Hospital Discharge			

3rd ck 786 6-1-81

Copied from new card I carry -
Model #253-04
Serial # 12955

PLEASE PAY LAST AMOUNT IN THIS COLUMN

THIS IS A COPY OF YOUR ACCOUNT AS IT APPEARS ON YOUR LEDGER CARD

Dx: Arteriosclerotic heart disease, cardiac decom

STATEMENT

pensation, cardiac arrhythmia, Osteoporosis & osteoarthritis of the spine, essential hyper tension, diabetes mell: itus

Eugene D. Liddy, M.D.
INTERNAL MEDICINE & CARDIOLOGY
MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET
SARASOTA, FLORIDA 33579

Mrs. Madeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
5/13/80	90060 office visi	$25.00	$25.00	
9/22	90060 office visit	$25.00	$25.00	
9/30	90070 ofc. v.polis	$30.00		
	81000 urine	$ 5.00	$35.00	
4/2/81	90060 office visi	$30.00	$30.00	00.00
5/13/81	Sarasota Memorial Hospital			
	90602 Consultation by requested			
	DR. R. Hoefer	$40.00		
5/14/81	90260 hospital Visi	$30.00		$70.00
	Diagnosis:			
	Defective pacemaker,			
	admitted for replacement of the			
	pulse generator.			

PLEASE PAY LAST AMOUNT IN THIS COLUMN

DX: A.S.H.D., CARDIAC DECOMP., CARDIAC ARRHYTHMIA ESSENTIAL HYPERTENSION, OSTEOPOROSIS & OSTEOARTHRITIS OF SPINE, DIABETES MELLITUS.

STATEMENT

Eugene D. Liddy, M.D.

INTERNAL MEDICINE & CARDIOLOGY

MEDICAL ARTS BLDG — 1950 ARLINGTON STREET

SARASOTA, FLORIDA 33579

8/31/81

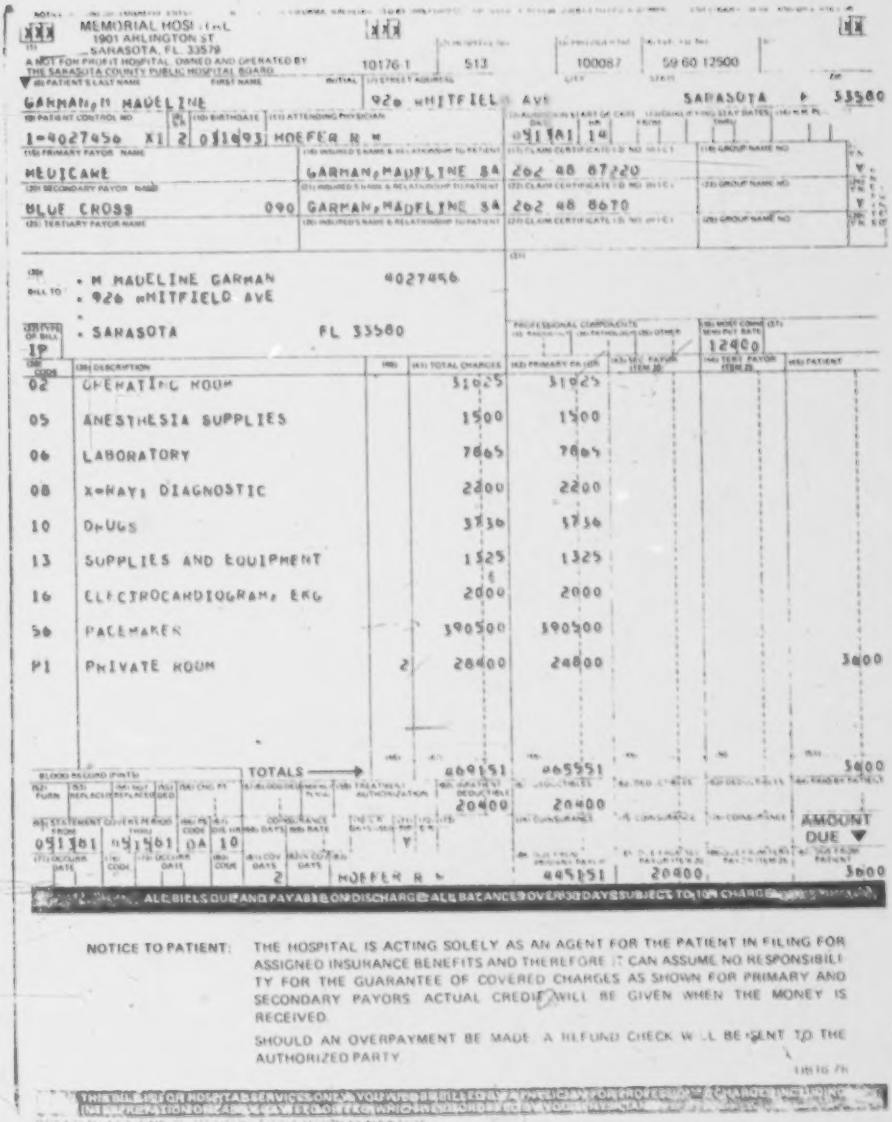
Mrs. Madeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
8/15/81 thru				
8/18/81	Hospital visits	$185.00		$185.00
8/15/81 90220 Initial hosp. care $90.00, 8/16 thru 8/17 daily follow up hosp. visits X 2 @ $30.00 per day, 8/18 90275 final hosp. visit & discharge summary $35.00 Admitted for covert cardiac decomp., hypokalemia.				

PLEASE PAY LAST AMOUNT IN THIS COLUMN



MEMORIAL HOSPITAL
1901 ARLINGTON ST
SARASOTA, FL 33578
A NOT FOR PROFIT HOSPITAL OWNED AND OPERATED BY THE SARASOTA COUNTY PUBLIC HOSPITAL BOARD

10176 1 | 513 | 100087 | 59 60 12500

PATIENT'S LAST NAME: GARMAN, M MADELINE
STREET ADDRESS: 926 WHITFIELD AVE
CITY: SARASOTA
STATE: FL
ZIP: 33580
PATIENT CONTROL NO: 1-4027456
SEX: X
BIRTHDATE: 1 2 05 16 93
ATTENDING PHYSICIAN: MOEFFER R W
DATE OF ADMISSION: 05 19 A1
HR: 14
PRIMARY PAYOR NAME: MEDICARE
INSURED'S NAME & RELATIONSHIP TO PATIENT: GARMAN, MADELINE SA
CLAIM CERTIFICATE I.D. NO: 262 48 8720
GROUP NAME NO:
SECONDARY PAYOR NAME: BLUE CROSS 090
INSURED'S NAME & RELATIONSHIP TO PATIENT: GARMAN, MADELINE SA
CLAIM CERTIFICATE I.D. NO: 262 48 8670
GROUP NAME NO:
TERTIARY PAYOR NAME:
INSURED'S NAME & RELATIONSHIP TO PATIENT:
CLAIM CERTIFICATE I.D. NO:
GROUP NAME NO:

BILL TO:
• M MADELINE GARMAN 4027456
• 926 WHITFIELD AVE
•
• SARASOTA FL 33580

TYPE OF BILL: 1P
MOST CURRENT REVISION DATE: 12400

REV CODE	DESCRIPTION	HCPCS	TOTAL CHARGES	PRIMARY PAYOR	SEC PAYOR	TERT PAYOR	PATIENT
02	OPERATING ROOM		31925	31925			
05	ANESTHESIA SUPPLIES		1500	1500			
06	LABORATORY		7065	7065			
08	X-RAY: DIAGNOSTIC		2200	2200			
10	DRUGS		3736	3736			
13	SUPPLIES AND EQUIPMENT		1325	1325			
16	ELECTROCARDIOGRAM: EKG		2000	2000			
50	PACEMAKER		390500	390500			
P1	PRIVATE ROOM		2 24800	24800			3000
	TOTALS →		469151	465551			3000

BLOOD PINTS: FURN | REPLACED | NOT REPLACED | ISSUED
BLOOD CHG | BLOOD NON-CHG
TREATMENT AUTHORIZATION
OUTPATIENT DEDUCTIBLE: 20400
COINSURANCE
AMOUNT DUE

STATEMENT COVERS PERIOD: FROM 05 13 01 THRU 05 19 01
ADMISSION HOUR: 0A
PRIORITY: 1
ADMISSION DATE
SOURCE
DISCHARGE HOUR
DISCHARGE DATE
STATUS CODE
COV DAYS: 2
LIFETIME RESERVE DAYS
MOEFFER R W

	469151	20400	3000

ALL BILLS DUE AND PAYABLE ON DISCHARGE. ALL BALANCES OVER 30 DAYS SUBJECT TO 10% CHARGE.

NOTICE TO PATIENT: THE HOSPITAL IS ACTING SOLELY AS AN AGENT FOR THE PATIENT IN FILING FOR ASSIGNED INSURANCE BENEFITS AND THEREFORE IT CAN ASSUME NO RESPONSIBILITY FOR THE GUARANTEE OF COVERED CHARGES AS SHOWN FOR PRIMARY AND SECONDARY PAYORS. ACTUAL CREDIT WILL BE GIVEN WHEN THE MONEY IS RECEIVED.

SHOULD AN OVERPAYMENT BE MADE, A REFUND CHECK WILL BE SENT TO THE AUTHORIZED PARTY.

THIS BILL IS FOR HOSPITAL SERVICES ONLY. YOU WILL BE BILLED BY A PHYSICIAN FOR PROFESSIONAL CHARGES INCLUDING CONSULTATIONS, SURGERY, ANESTHESIA, X-RAY, EKG, LABORATORY, ETC. WHICH ARE NOT SHOWN ON THIS BILL.

[illegible] HOSPITAL, SARASOTA FLA. ITEMIZED LIST O CHARGES
A NOT FOR PROFIT HOSPITAL
LICENSED BY THE STATE OF FLORIDA 05/22/8.

ATIENT: 4027456 GARCIA, [illegible] ADMITTED 05/13/81 DISCHARGED 5/15/8

QTY	DEPT	DESCRIPTION	TOTAL	CHG CODE	TRAN #
01	LAB	SMA 6			0001
01	LAB	SMA-12			0002
01	LAB	RAPID PLASMA REAGIN (RPR) RPR			0003
01	LAB	PARTIAL THROMBO			0004
01	LAB	[illegible] TIME			0005
01	LAB	CBC			0006
01	LAB	UA-ANALYSIS COMPLETE			0007
01	LAB	ELECT-CARDIOGRAM			0008
01	ROOM	PRIVATE ROOM		6TA-675 A	0009
01	RAD	CHEST 2 V & LAT-INPATIENT			0010
11	SR	SURGERY			0011
01	AN	ANESTHESIA LOCAL			0012
01	DR	PACEMAKER INSERTION-CYBERLITH			0013
01	CSS	SE DEXTROSE IV PATENT ADVICE			0014
01	CSS	BLOOD SET			0015
02	CSS	SHAVE PREP PACK			0016
01	LAB	ELECTROCARDIOGRAM			0017
01	ROOM	PRIVATE ROOM		6TA-675 A	0018
01	CSS	ANGIOCATH IV PLACEMENT UNIT			0019
04	PHM	PROPRANOLOL 40MG			0020
01	PHM	DRUGS			0021
01	PHM	OS-CAL TABS			0022
01	PHM	ASCORBIC ACID 500 MG TABS 0.20			0023
04	PHM	CEPHALEXIN CAPS 500MG 4			0024
01	PHM	MAALOX 180ML BOTTLE			0025
01	PHM	FLURAZEPAM CAPS 15MG ORAL			0026
01	PHM	CEPHAPIRIN 2GM IVPB IN SAVE DS			0027
01	PHM	DEXTROSE 5% INJ 100CC [illegible]			0028
01	PHM	PROMETHAZINE 25MG INJ TO 1 MED			0029
01	PHM	MEPERIDINE INJ 25MG 1ML			0030

MEMORIAL HOSPITAL, SARASOTA FLA. ITEMIZED LIST O CHARGES
A NOT FOR PROFIT HOSPITAL
LICENSED BY THE STATE OF FLORIDA 09/09/81

PATIENT: 0207730 GARMAN,M MADELINE ADMITTED 08/15/81 DISCHARGED /19/8

QTY	DEPT	DESCRIPTION	TOTAL	CHG CODE	TRAN #
01	LAB	ELECTROCARDIOGRAM			0001
01	LAB	URINALYSIS COMPLETE			0002
01	LAB	SMA 6			0003
01	LAB	COMPLETE BLOOD COUNT			0004
01	ROOM	PRIVATE ROOM			0005
01	RAD	CHEST P A & LAT-INPATIENT		2NE-255 A	0006
01	LAB	ANTI-NUCLEAR ANTIBODY			0007
01	LAB	DIGOXIN			0008
01	LAB	SMA 6			0009
01	LAB	SMA-12			0010
01	ROOM	PRIVATE ROOM			0011
01	LAB	ELECTROCARDIOGRAM		2NE-255 A	0012
01	ROOM	PRIVATE ROOM			0013
01	LAB	SMA 6		2NE-255 A	0014
01	ROOM	PRIVATE ROOM			0015
02	PHM	PROPRANOLOL 40MG		2NE-255 A	0016
15	PHM	OS-CAL TABS			0017
04	PHM	ASCORBIC ACID 500 MG TABS 0.80			0018
04	PHM	DIGOXIN 0.125MG TABS			0019
14	PHM	PROPRANOLOL TABS 10MG			0020
06	PHM	POTASSIUM CHLORIDE 10MEW TAB			0021
01	PHM	DRUGS			0022
01	PHM	MAALOX 180ML BOTTLE			0023

Form HCFA-1533 (6-80) (Formerly SSA-1533)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES/HEALTH CARE FINANCING ADMINISTRATION

MEDICARE HOSPITAL, EXTENDED CARE AND HOME HEALTH BENEFITS RECORD

100087

DATE: 06/19/81

MADELINE GARMAN
926 WHITFIELD AVE
SARASOTA FL 33580

HEALTH INSURANCE CLAIM NUMBER
262-48-8722D

Always use this number when writing about your claim.

No action is required of you upon receipt of this notice. This notice is to give you a record of the Medicare benefits you used during the period shown in Item 1. For important additional information please see the other side of this form.

1 OUR RECORDS SHOW THAT YOU RECEIVED THESE SERVICES

Type of Services	Services Were Provided By	Date
INPATIENT HOSPITAL	MEMORIAL HOSP 1901 ARLINGTON ST SARASOTA FL 33579	05/13/81 THRU 05/15/81

2 MEDICARE HAS PAID FOR ALL COVERED SERVICES EXCEPT

$204.00 FOR THE INPATIENT DEDUCTIBLE.

IF YOU HAVE ANY QUESTIONS ABOUT THIS RECORD PLEASE GET IN TOUCH WITH:

BLUE CROSS & BLUE SHIELD OF FLORIDA
PO BOX 2711
JACKSONVILLE FL 32203
TELEPHONE NUMBER: 1-904-791-6260

3 OUR RECORDS SHOW THE FOLLOWING BENEFITS WERE USED THIS TIME

Inpatient Hospital Days	Lifetime Reserve Days	Extended Care Days	Home Health Visits Hospital Insurance	Home Health Visits Medical Insurance
2				

APPENDIX I

1
DEN REPORTS FOR ALL PACEMAKERS

ACCESS REPORT DATE PRODUCT MANUFACTURER

12264 090877 PACEMAKER AMERICAN TECHNOLOGY INC
TEXT PACEMAKER WAS IMPLANTED IN AUGUST, 1976 AND FAILED ON SEPTEMBER 7, 1977. THE UNIT WAS REPLACED THAT SAME DAY (MORE)
FINAL PROBLEM ASSESSMENT

12259 010378 PACEMAKER AMERICAN TECHNOLOGY
TEXT REPORTER STATES THAT HE AND SEVERAL OF HIS COLLEAGUES HAVE RECENTLY EXPERIENCED BURNOUT PROBLEMS WITH THESE PACEMAKERS. ACCORDING TO REPORTER, THESE PACEMAKERS ARE REPORTEDLY REPLACEMENTS FOR THOSE RECALLED BY THE FIRM SEVERAL MONTHS AGO DUE TO A SIMILAR PROBLEM. (MORE)
FINAL PROBLEM ASSESSMENT

12390 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE WAS 10/1/76, FAILED 7/29/77. MALFUNCTION NOTED RATE DECREASED FROM 66.4 BPM TO 64.1 BPM. PACER RETURNED TO MANUFACTURER (MORE)
FINAL PROBLEM ASSESSMENT

12391 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 10/27/76, FAILURE DATE 8/9/77. MALFUNCTION NOTED: NO OUT-PUT. PACER RETURNED TO MANUFACTURER (MORE)
FINAL PROBLEM ASSESSMENT:

12392 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 10/21/76, FAILURE DATE 11/22/77. MALFUNCTION NOTED NO OUT-PUT. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT:

12393 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 10/20/76, FAILURE DATE 11/28/77. MALFUNCTION NOTED: LOSS OF SENSING. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT:

12394 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 7/6/76, FAILURE DATE 10/26/77. MALFUNCTION NOTED LOSS OF SENSING AND LOSS OF CAPTURE. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT:

12395 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY PRIOR TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT NA

12396 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 7/29/77, FAILURE DATE 9/7/77. MALFUNCTION NOTED: NO OUT-PUT. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12397 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY IMPLANT DATE 4/9/77, FAILURE DATE 9/2/77. MALFUNCTION NOTED RATE DECREASE. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12398 011078 PACEMAKER AMERICAN TECHNOLOGY
TEXT THIS IS ONE OF NINE COMPLAINTS RECEIVED FROM THE PACEMAKER REGISTRY. IMPLANT DATE 6/9/77, FAILURE DATE 11/26/77. MALFUNCTION NOTED: NO OUTPUT. PACER RETURNED TO MANUFACTURER. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12584 060178 PACEMAKER AMERICAN TECHNOLOGY
TEXT PATIENT HAD 3 PACEMAKERS IMPLANTED WITHIN A PERIOD OF 14 MONTHS. THE FIRST WAS EXPLANTED DUE TO BATTERY DEPLETION RESULTING FROM A SHORT IN A TANTALUM CAPACITOR. THE SECOND WAS EXPLANTED DUE TO BATTERY MALFUNCTION. (MORE)
FINAL PROBLEM ASSESSMENT:

12799 102678 PACEMAKERS AMERICAN TECHNOLOGY
TEXT COMPLETE OUTPUT FAILURE PRE-OP. PECTORAL MUSCLE TWITCHING. FAILURE TO SENSE PROPERLY. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12775 103078 MICRO-7 & MICRO-12 CARDIAC PACEMAKERS AMERICAN TECHNOLOGY
TEXT DR. IS AWARE OF 30 AMTECH PACERS THAT WERE SUBJECT TO PREMATURE FAILURE BECAUSE OF POSSIBLE CAPACITOR PROBLEM. (MORE)
FINAL PROBLEM ASSESSMENT:

12861 121878 PACEMAKER AMERICAN TECHNOLOGY
TEXT COMPLAINANT STATES THAT MANUFACTURER DID NOT SEND THEM A "DEAR DOCTOR" LETTER UNTIL 3 MONTHS AFTER IT WAS ISSUED. COMPLAINANT ALSO STATES THAT HE IS AWARE OF EXCESSIVE FAILURE RATE OF PACEMAKERS WHICH WERE NOT INCLUDED IN MANUFACTURER'S RECALL. (MORE)
FINAL PROBLEM ASSESSMENT:

12916 022279 SAFT LITHIUM BATTERIES/PACEMAKER AMERICAN TECHNOLOGY
TEXT REPORTER STATES HIS EUROPEAN COLLEAGUES HAVE BEEN EXPERIENCING THE SAFT LITHIUM BATTERIES, WHICH ARE INCORPORATED IN PERMANENT CARDIAC PACEMAKERS, FAILING SOONER THAN EXPECTED. (MORE)
FINAL PROBLEM ASSESSMENT: NA

35020 110279 PACEMAKER AMERICAN TECHNOLOGY
TEXT 2 PACEMAKERS HAVE FAILED IN THE SAME PT. ONE WAS PLACED ON 8/12/78 AND IT FAILED ON 7/13/79. IT WAS REPLACED WITH ANOTHER ON 8/2/79, BUT IT ALSO FAILED ON 10/29/79. THE FIRST PACEMAKER WAS PROBABLY RETURNED TO THE CO. BECAUSE THEY ISSUED A CREDIT TO PT., HOWEVER, THE SECOND PACEMAKER IS BEING HELD FOR EXAMINATION. ANOTHER SURGEON IN THE AREA HAS HAD A PACEMAKER FAILURE IN THE LAST 3 MONTHS. THIS WARRANTS INVESTIGATION I BELIEVE. (CONDENSED
FINAL PROBLEM ASSESSMENT:

11009 062776 ARCO LITHIUM PACEMAKER ARCO MEDICAL PRODUCTS CO
TEXT IMPLANTED TEN MONTHS. WAS EXPLANTED DUE TO IT'S INABILITY TO PACE. PACER WAS RETURNED TO THE COMPANY AND THEIR ANALYSIS CONCLUDED THAT THE FAILURE WAS DUE TO BRIDGING ACROSS THE FEED THROUGH AS A RESULT OF CHEMICAL RESIDUES LEFT AFTER CLEANING. CO. LETTER STATED THAT THEY INSTITUTED CORRECTIVE ACTION BY INFORMING OPERATORS IN THE CLEANING PROCESS, ADDING AN ADDITIONAL CLEANING STEP AND BY REQUIRING VISUAL INSPECTION OF THE ISOLATION GAP TO INSURE .025" MINIMUM CLEARANCE. (MORE)
FINAL PROBLEM ASSESSMENT

[illegible] 070577 ARCO LI-3 PULSE GENERATOR ARCO MEDICAL PRODUCTS
TEXT PATIENT FIBRILLATED WHEN PACER WAS IMPLANTED. PACER WAS OPERATING AT ABOUT 1500 EPM. A 2ND PACER WAS USED WITH NO ADDITIONAL PROBLEMS. PACER WAS RETURNED TO THE FIRM FOR FAILURE ANALYSIS. (MORE)
FINAL PROBLEM ASSESSMENT:

30577 053177 CARDIAC PACE MAKER ARCO MEDICAL PRODUCTS
TEXT WE HAD NON STERILE GLUE IN A CONTAINER WITH STERILE PACEMAKER AND OTHER PRODUCTS. GLUE WAS IN A CYLINDER TYPE CONTAINER AND THE NON-STERILE LABEL WAS NOT VISABLE AT ONE TIME.
FINAL PROBLEM ASSESSMENT:

32173 070578 PACEMAKER ARCO MEDICAL PRODUCTS
TEXT PACER FAILED 9 MONTHS AFTER INITIAL IMPLANT.
FINAL PROBLEM ASSESSMENT: BATTERY FAILURE/FIRM TESTING SHOWED BATTERIES DEPLETED DUE TO SHORT CIRCUIT/CHANGE IN HEAT TREATMENT OF SUBSTRATE MATERIAL CORRECTED PROBLEM.

32253 071778 ARCO CARDIAC PACER/LITHIUM TYPE ARCO MEDICAL PRODUCTS
TEXT PACER JUST STOPPED WORKING SUDDENLY ONE MORNING. PACER IMPLANTED 11/22/75 AND WAS REMOVED 6/10/77. PACEMAKER WAS GUARANTEED FOR 6 YEARS.
FINAL PROBLEM ASSESSMENT: NA

13259 062679 DEMAND PACEMAKER ARCO MEDICAL PRODUCTS
TEXT COMPLAINANT'S SISTER HAD A PREMATURE (1 YEAR 4 MONTHS) FAILURE OF CARDIAC PACEMAKER. (CONDENSED)
FINAL PROBLEM ASSESSMENT: FIRM F/U REVEALED PREMATURE FAILURE APPARENTLY DUE TO LEAD-TISSUE INTERFACE PROBLEM AND NOT DUE TO FAILURE OF PULSE GENERATOR/INFO BASED ON INFO FROM MED RECORDS AND AS UNIT WAS NOT RETURNED.

13464 010980 L1-3D (ARCOLITH 4) PACEMAKER ARCO MEDICAL PRODUCTS CO.
TEXT COMPLAINT CONCERNS 10 CASES OF EARLY FAILURES OF PACEMAKER. IN ALL 10 CASES THE REASON OF REMOVAL WAS SUDDEN LOSS OF OUTPUT AND THE REASON OF FAILURE WAS SUPPOSEDLY EARLY DEPLETION OF BATTERIES. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

13622 090679 LITHIUM THIONYL CHLORIDE PLUSE GENERATOR
ARCO MEDICAL PRODUCTS
TEXT: THE END-OF-LIFE-INDICATOR (EOL1) DOES NOT PERFORM AS ORIGINALLY ESTIMATED ON ARCOLITH-3, ARCOLITH-4, AND LI-3 PACEMAKERS. ALTHOUGH THESE PACEMAKERS ARE EXPECTED TO REACH THE END OF THEIR DESIGN LIFETIME, THE EOL1 WHICH SIGNALS APPROACHING BATTERY DEPLETION DOES NOT FUNCTION AS ORIGINALLY STATED IN FIRMS MANUAL. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

37216 092980 ARCO DEMAND PACEMAKER ARCO MEDICAL PRODUCTS CO
TEXT ABRUPT PACEMAKER FAILURE FOLLOWING SUCCESSFUL DEFIBRILLATION OF PT FROM CARDIAC ARREST. SUSPECT DEFIBRILLATION DAMAGED CIRCUITRY OF PACEMAKER. PACEMAKER IS SUPPOSED TO BE DESIGNED TO BE PROTECTED AGAINST THIS. MANUF NOTIFIED, PRODUCT SENT TO MANUF FOR ANALYSIS.
FINAL PROBLEM ASSESSMENT: FIRMS FINDINGS ARE THAT THIS IS AN ISOLATED INCIDENT ASSOCIATED WITH PACEMAKER DESIGN AND USER POSITIONING THE DEFIB PADDLER TOO CLOSE TO THE GENERATOR.

37060 090280 PHRENIC NERVE PACEMAKER AVERY LABS
TEXT: THIS DEVICE IS SOLE RESPIRATORY SUPPORT FOR HIGH CERVICAL QUADRAPLEGIC PTS. BATTERY FAILED SUDDENLY ABOUT 2 HOURS AFTER INSTALLATION, CAUSING PT TO STOP BREATHING. INSPECTION REVEALED ACCUMULATION OF WHITE POWDERY SUBSTANCE NEAR NEG TERMINAL. MALLORY STATED THAT MANUF WAS HAVING PROBLEMS WITH ELECTROLYTE LEAKAGE FROM BATTERY. NOTIFIED MANUF. OTHER POTENTIAL USERS OF THIS BATTERY SHOULD BE INFORMED TO PREVENT SIMILAR OCCURRENCES.
FINAL PROBLEM ASSESSMENT: COMPLAINANT DISSATISFIED WITH INTERIM MODIFICATION KIT TO GROUND EXCESSIVE STATIC, BUT TECH WHO TESTED THAT COULD NOT

FIND SIGNIFICANT LEAKAGE. REMOSOL THAT RECENTLY REDESIGNED TO INCORPORATE A GROUNDING STRAP AS A STANDARD ITEM.

10439 041676 IMPLANTABLE CARDIAC PULSE GEN BIOTRONIC LABS
TEXT: RECURRENT PROBLEMS ENGAGING THE PROXIMAL ELECTRODE TIP INTO THE PULSE GENERATOR HOUSING THIS OCCURRED ON MORE THAN ONE PACEMAKER INSERTION AND HAS CAUSED US TO DISCONTINUE ITS USE. DESPITE OUR PROBLEMS THE COMPANY HAS SHOWN NO INTEREST IN MODIFYING THEIR "DAYNET" CONNECTION.
FINAL PROBLEM ASSESSMENT:

12659 121176 PACEMAKER/NUCLEAR POWERED BIOTRONIK SALES
TEXT COMPLAINANT STATES SHE IS CONCERNED ABOUT THE APPARENT HIGH FAILURE RATES OF SOME MODELS OF THIS MANUFACTURER'S PACEMAKER. COMPLAINANT STATES THESE UNITS MAY HAVE A "CAPTURE" PROBLEM. (CONDENSED)
FINAL PROBLEM ASSESSMENT:

12924 022779 ELECTRODE SEAL FOR PACEMAKERS BIOTRONIK
TEXT REPORTER FEELS THERE IS A DESIGN DEFECT IN PACEMAKER GENERATOR UNITS WHICH LEADS TO DELAYED SKIN EROSION UP TO 36 MONTHS FOLLOWING IMPLANTATION. THE CAUSE OF THE EROSION APPEARS TO BE A LEAK BETWEEN THE ELASTIC ELECTRODE AND THE PACEMAKER GENERATOR UNIT AT THE INSERTION OF THE LEAD INTO THE PACEMAKER UNIT. (MORE)
FINAL PROBLEM ASSESSMENT:

11314 102076 CARDIAC PACEMAKER CARDIAC PACEMAKERS
TEXT PACEMAKER IMPLANTED 10/27/75. ON 9/14/76 PACEMAKER FAILED PREMATURELY. (MORE)
FINAL PROBLEM ASSESSMENT:

11317 102076 CARDIAC PACEMAKER CARDIAC PACEMAKERS INC
TEXT PACER WAS IMPLANTED 2/10/75, AND FAILED 4/6/76, AS A RESULT OF LOSS OF SENSING, LOSS OF CAPTURE AND RATE DECREASE. THE PHYSICIANS REPORTED THAT THE PACER PATIENT HAD BEEN DEFIBRILLATED PRIOR TO EXPLANTATION. (MORE)
FINAL PROBLEM ASSESSMENT:

12210 070677 CARDIAC PACEMAKER CARDIAC PACEMAKERS INC
TEXT 9/26/75 A CARDIAC PACEMAKER WAS IMPLANTED IN PATIENT. THE PACEMAKER HAD LITHIUM TYPE BATTERIES AND WAS GUARENTEED FOR FIVE YEARS. PATIENT DEVELOPED PAINS IN CHEST AND ARM. ON 6/29/77, DOCTOR REMOVED THE CARDIAC PACEMAKER AND REPLACED IT WITH A METRONIC PACEMAKER. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12253 081077 LITHIUM-IODINE PULSE GENERATOR CARDIAC PACEMAKERS INC
TEXT PATIENT SUFFERED FROM A "RUNAWAY" PACEMAKER. THE PATIENT WAS IN THE CARDIAC UNIT AT THE TIME AND THE WIRE WAS DISCONNECTED THROUGH A LOCAL INCISION. ATTEMPTS TO OVERIDE THE PERMANENT PACEMAKER WITH A TEMPORARY ONE WERE UNSUCCESSFUL. NO ADVERSE EFFECTS RESULTED TO THE PATIENT FROM THIS INCIDENT. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12602 061676 PACEMAKER CARDIAC PACEMAKER
TEXT PATIENT CAME TO HOSPITAL WITH NO OUTPUT FROM PACEMAKER. BENCH TEST CONFIRMED NO OUTPUT AND REVEALED COMPONENT MALFUNCTION AS CAUSE. IMPLANT DATE 3/31/76, FAILURE DATE 5/30/76.
FINAL PROBLEM ASSESSMENT:

12603 020276 PACEMAKER CARDIAC PACEMAKER
TEXT PACER FAILS TO SENSE. AT EXPLANT, OUTPUT WAS DOWN 2.6 OPEN CIRCUIT. IMPLANT DATE 11/4/77, FAILURE DATE 2/2/76.
FINAL PROBLEM ASSESSMENT:

12604 061676 PACEMAKER CARDIAC PACEMAKER
TEXT PATIENT ADMITTED TO EMERGENCY ROOM. PACEMAKER CEASED FUNCTIONING. WOULD NOT PACE PATIENT EXCEPT WHEN MAGNET WAS APPLIED. BENCH TEST REVEALED A COMPONENT MALFUNCTION. IMPLANT DATE 5/13/76, FAILURE DATE 4/11/76.

FINAL PROBLEM ASSESSMENT:

12691 C12479 PACEMAKER/UNIPOLAR DEMAND CARDIAC PACEMAKERS
TEXT REPORTER STATES HE IS HAVING TROUBLE WITH THE INSULATION AROUND THE BATTERY. CAN FEEL IMPULSE IN THE MUSCLE GOING INTO RIGHT SHOULDER AND ARM. DR. IMPLANTED A "ECCI" ON PACEMAKER. BUT PAIN CONTINUED. (CONDENSED)
FINAL PROBLEM ASSESSMENT: NA

12699 021479 PACEMAKER (PROGRAMMABLE) CARDIAC PACEMAKERS
TEXT: DOCTOR CALLED AND STATED A PATIENT HAD DIED DUE TO THE FACT ANOTHER DOCTOR HAD PROGRAMMED THE PACEMAKER TOO LOW. THIS DOCTOR FEELS THAT THE FACT THAT THEY CAN BE PROGRAMMED IS A SAFETY HAZARD.
FINAL PROBLEM ASSESSMENT: NA

12923 022779 ELECTRODE SEAL FOR PACEMAKERS CARDIAC PACEMAKERS
TEXT: REPORTER FEELS THERE IS A DESIGN DEFECT IN PACEMAKER GENERATOR UNITS WHICH LEADS TO DELAYED SKIN EROSION UP TO 36 MONTHS FOLLOWING IMPLANTATION. THE CAUSE OF THE EROSION APPEARS TO BE A LEAK BETWEEN THE SILASTIC ELECTRODE AND THE PACEMAKER GENERATOR UNIT AT THE INSERTION OF THE LEAD INTO THE PACEMAKER UNIT. (MORE)
FINAL PROBLEM ASSESSMENT SMALL PERCENTAGE OF COMPLAINTS ON EROSION/REPOR DECREASED WEIGHT OF NEWER MODELS

13237 012679 CARDIAC PACEMAKER CARDIAC PACEMAKER
TEXT COMPLAINANT STATES THAT HER FATHER HAD A PACEMAKER IMPLANTED ON 5/15/75 AND APPROXIMATELY 2 MONTHS LATER HE DIED. COMPLAINANT STATES THAT HER FATHER TOLD HER THAT HIS PACEMAKER "NEVER WORKED RIGHT".
FINAL PROBLEM ASSESSMENT:

13316 100879 PACEMAKER LITHIUM UNIPOLAR DEMAND CARDIAC PACEMAKERS, INC.
TEXT PACEMAKER HAS A 4 YEAR GUARENTEE. IMPLANTED ON 4/22/77, FAILED AND HAS TO BE EXPLANTED ON 9/20/79.
FINAL PROBLEM ASSESSMENT:

13325 091079 UNIPOLAR PACEMAKER/PROGRAMMABLE CARDIAC PACEMAKER INC.
TEXT: PACEMAKER FAILURE: UNIT INITIALLY IMPLANTED 5/2/79, EXPLANTED 9/1/79 DUE TO UNIT FAILURE.
FINAL PROBLEM ASSESSMENT:

15590 032682 PACEMAKER CARDIAC PACEMAKERS INC
TEXT: REPORTER CLAIMS HER FATHER HAD A PACEMAKER IMPLANTED ON 2/15/61 & DIED ON 10/21/61. DECEASED WAS HOSPITALIZED 7 WEEKS & UNDERWENT 4 SEPARATE OPERATIONS WHICH INVOLVED 2 SEPARATE PACEMAKERS. CLAIMS CORONER'S REPORT STATED DEATH WAS RESULT OF PACEMAKER FAILURE. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

15361 011882 HEART AID/DEFIB & EXTERNAL PACEMAKER CARDIAC RESUSCIATOR CORP
TEXT THIS DEVICE IS A COMBINATION DEFIBRILLATOR & EXTERNAL PACEMAKER. REPORTER STATES THAT THE DEVICE APPARENTLY DELIVERED A DEFIBRILLATION SHOCK AT AN IMPROPER TIME TO A CONSCIOUS PATIENT THIS TYPE OF INCIDENT REPRESENTS A SERIOUS HAZARD.
FINAL PROBLEM ASSESSMENT:

15364 102579 PACEMAKER CORATOMIC, INC.
TEXT: REPORTER CALLED AND STATED THAT A RECENTLY IMPLANTED PACEMAKER HAD FAILED.
FINAL PROBLEM ASSESSMENT: 29 FAILURE REPORTS. 13 INVOLVED RANDOM CELL FAILURE CAUSED BY STRESS CRACKS. 16 WITHIN SPEC BUT EXPLANTED DUE TO ACCELERATED DEPLETION. NEWER MODEL CORRECTED THIS

15360 101579 PACEMAKER L-600 CORATOMIC, INC.
TEXT: RN CALLED TO REPORT SUDDEN LOSS IN ENERGY IN SUBJECT PACEMAKERS. A PT THAT HAD RECEIVED 1 OF THE SUBJECT PACEMAKERS APPROX 1½ MONTHS AGO HAS

BEING MONITORED. BETWEEN SEP. AND OCT., THE RATE DROPPED FROM 66 TO 56. THE PACEMAKER WAS REMOVED AND REPLACED WITH A DIFFERENT BRAND. THE DEVICES SHOULD HAVE A LIFE SPAN OF OVER 5 YEARS AND THIS RECENT CASE HAD DROPPED IN ENERGY AFTER ONLY 1 YEAR. HOSPITAL HAS WRITTEN TO MFGR. 2 TIMES BUT HAS RECEIVED NO RESPONSE. (SEE FILE)
FINAL PROBLEM ASSESSMENT: FIRM HAD REVISED ITS ORIGINAL CALCULATION OF ESTIMATED LIFE EXPECTANCY FOR THIS MODEL. THE L-500 IS AN OBSOLETE MODEL. FIRM UNABLE TO EVALUATE FAILURES IN THE ABSENCE OF RETURNED PACEMAKER. FIRM SEES NO TRENDS IN FAILURE.

13400 110679 PACEMAKER/L-500 CORATOMIC, INC.
TEXT: DOCTOR REPORTED THAT 3 OF 11 PACEMAKERS HAD EXPERIENCED A RATE SLOWDOWN PREDICTIVE OF BATTERY DEPLETION BEFORE 24 MONTHS IN USE. DOCTOR FEELS THIS IS A VERY POOR RECORD FOR A DEVICE THAT IS PREDICTED TO LAST 5½ YEARS. (SEE FILE)
FINAL PROBLEM ASSESSMENT: 29 FAILURE REPORTS. 13 INVOLVED RANDOM CELL FAILURE CAUSED BY STRESS CRACKS. 16 WITHIN SPEC BUT EXPLANTED DUE TO ACCELERATED DEPLETION. NEWER MODEL CORRECTED THIS

13401 110579 PACEMAKER/L-500 CORATOMIC, INC.
TEXT: A DOCTOR AT THE REGISTRY REPORTS HE HAS SEEN A SLIGHT TREND AMONG THE 21 L-500'S HE IS FOLLOWING. HE IS PUTTING THOSE PT'S. ON WEEKLY MONITORING AFTER 18 MONTHS IN USE. ANOTHER DOCTOR THERE HAS ALSO EXPERIENCED A SLIGHTLY EXCESSIVE SLOWDOWN AMONG THE 30 PT'S. HE IS FOLLOWING (SEE FILE).
FINAL PROBLEM ASSESSMENT: 29 FAILURE REPORTS. 13 INVOLVED RANDOM CELL FAILURE CAUSED BY STRESS CRACKS. 16 WITHIN SPEC BUT EXPLANTED DUE TO ACCELERATED DEPLETION. NEWER MODEL CORRECTED THIS

13404 102479 PACEMAKER/L-500 CORATOMIC, INC.
TEXT: THIS COMPLAINT CONCERNS THE DEGENERATION OF THE POWER SOURCE FOR THE L-500 PACEMAKER. THE PT. IS SCHEDULED FOR SURGERY ON 11/2/79 FOR THE PURPOSE OF REMOVAL AND REPLACEMENT OF A PACEMAKER. THIS IS THE THIRD PACEMAKER MANUFACTURED BY THE SAME FIRM THAT HAS BEEN OR WILL BE EXPLANTED WITHIN 13 MONTHS.
FINAL PROBLEM ASSESSMENT: 29 FAILURE REPORTS. 13 INVOLVED RANDOM CELL FAILURE CAUSED BY STRESS CRACKS. 16 WITHIN SPEC BUT EXPLANTED DUE TO ACCELERATED DEPLETION. NEWER MODEL CORRECTED THIS

13566 050680 LITHIUM PACEMAKER CORATOMIC PACEMAKER INC
TEXT: PACEMAKER WAS IMPLANTED ON 10/03/78 AND HAD TO BE EXPLANTED ON 02/29/80 BECAUSE OF PREMATURE DEPLETION OF THE LITHIUM POWER SOURCE.
FINAL PROBLEM ASSESSMENT:

14371 103180 PACEMAKER L500 CORATOMIC, INC.
TEXT: INFO FROM FRANCE: CORATOMIC ALERTED AMERICAN PHYSICIANS OF RISK OF SUDDEN EOL OF L500PMS AUG 8/80. REPLACEMENT ADVISED. CAUSE OF DEFECT WOULD APPEAR TO BE POOR PERFORMANCE OF THE MALLORY L1/PE12 BATTERY. BATTERY MAY SUDDENLY RUN DOWN WHEN ONLY ONE OF ITS ELEMENTS HAS BEEN DISCHARGED. (CONDENSED)
FINAL PROBLEM ASSESSMENT: NA

14565 012881 CYCLITH-P PACEMAKER CORATOMIC,INC.
TEXT: PACEMAKER WAS IMPLANTED ON 6/5/80 & ON 1/21/81 THE PACEMAKER HAD TO BE EXPLANTED BECAUSE IT HAD REACHED "END OF LIFE" CHARACTERISTICS. (SEE FILE)M
FINAL PROBLEM ASSESSMENT: FIRM BELIEVES THE PROBLEM WAS PROBABLY BATTERY DEPLETION DUE TO A CIRCUIT PROBLEM, BUT THEY COULD NOT BE SURE WITHOUT EXAMINATION OF THE PACEMAKER.

14903 043081 PACEMAKER/R-WAVE VV1 LITHIUM CORATOMIC, INC
TEXT: COMPLAINANT STATED THAT 2 OF HER PATIENTS THAT SHE IS MONITORING HAVE PACERS THAT ARE FAILING. BOTH PACERS WERE IMPLANTED IN 12/78. ONE SET AT 71.2 BEATS BPM. WHICH NOW READS 66.5 BPM. SHE STATED THAT THE PACER LITERATURE STATES THAT THE PACER WILL EXCEED 10 YRS AT 100% PACING, WHILE THESE HAVE BEEN IN PLACE ONLY 28 MONTHS.(SEE FILE)

FINAL PROBLEM ASSESSMENT: FIRMS RECORDS REVEALED THAT UNITS HAVE NEVER BEEN EXPLANTED OR RETURNED TO THEM. FIRM BELIEVES RATE DROP COULD BE DUE TO BATTERY DECAY OR STABILIZATION OF ELEC. COMPONENTS. 16 OTHER COMPLAINTS IN FILE.

26775 102661 CORATOMIC PACEMAKER CORATOMIC
TEXT: IMPLANTED 7/11/61 WITH PROJECTED BATTERY LIFE AT 8-10 YRS. BATTERY FAILURE DOCUMENTED 10/21/61, PACER REMOVED & REPLACED WITH A DIFFERENT MAKE.
FINAL PROBLEM ASSESSMENT:

10136 070676 KAPPA STANICAR PACEMAKER CORDIS DOW
TEXT DROP IN PACEMAKER RATE, REPLACED ON 6-17-76.
FINAL PROBLEM ASSESSMENT:

00001 122375 PACEMAKER CORDIS DOW
TEXT: BELIEVED THAT A STANICOR DEMAND PACEMAKER WAS ASSOCIATED WITH THE DEATH OF A PATIENT. FELT THAT THERE IS AN ELECTROMAGNETIC PROBLEM. ALL PACEMAKERS, EXCEPT A 211ACONE, MALFUNCTIONED WITHIN 4 FEET OF A TRACTOR WHEN TESTED.
FINAL PROBLEM ASSESSMENT:

30506 062977 OMNI-STANICOR PACEMAKER CORDIS DOW
TEXT: PATIENT TRANSFERRED TO HOSPITAL FOR SYNCOPAL EPISODE. NOTED ON ADMISSION TO HAVE HEART RATE OF UP TO 300/MIN DUE TO RUNAWAY PACEMAKER AT A-RATE VARYING FROM 300-500/MIN. PROBLEM WAS RESOLVED ONLY BY CUTTING PACEMAKER WIRE DURING CARDIAC RESUSCITATIVE MEASURES. THIS WAS CLEARLY A LIFE THREATENING COMPLICATION OF THIS DEVICE. I HAVE FOUND A SIMILAR CASE REPORT OF A SIMILAR COMPLICATION WITH THIS MODEL. UNIT WAS RETURNED TO CORDIS. I HAVE RECEIVED NO INFORMATION FROM THEM. (MORE
FINAL PROBLEM ASSESSMENT:

30499 062777 CORDIS PACEMAKER CORDIS DOW
TEXT: THE COMPANY'S WARRANTY SHOULD BE INVESTIGATED. IT SPECIFIES THAT IF A UNIT FAILS, THEIR WARRANTY ONLY APPLIES IF THE UNIT IS REPLACED USING ANOTHER CORDIS UNIT. TRY TO EXPLAIN THAT TO A PATIENT SOMETIME.
FINAL PROBLEM ASSESSMENT: NA

31229 111477 PACEMAKER CORDIS DOW
TEXT THE MANUFACTURERS OF THE CORDIS PACEMAKER APPARENTLY RECOMMEND VERY FREQUENT PACEMAKER CHECKS FOLLOWING A SCHEDULE ALLEGEDLY RECOMMENDED BY THE SOCIAL SECURITY ADMINISTRATION. IF INDEED, THE CORDIS PACEMAKER MUST BE CHECKED WEEKLY AFTER 18 MONTHS, THIS IS CONTRARY TO THE ANTICIPATED LIFE OF WELL OVER 3 TO 4 YEARS. THIS MAY REPRESENT EXCESSIVE EXPENSE AND INAPPROPRIATE USE OF MEDICAL TECHNOLOGY. (MORE)
FINAL PROBLEM ASSESSMENT NA

31308 121277 PROGRAMMABLE PACEMAKER CORDIS DOW
TEXT PREMATURE BATTERY FAILURE IN 3 PATIENTS IN LESS THAN ONE YEAR FOLLOWING IMPLANTATION.
FINAL PROBLEM ASSESSMENT: 1 PACER WORKING NORMALLY. 1 PACER FAILED DUE TO BATTERY DEPLETION CAUSED BY A SHORT. FIRM CONSIDERS RANDOM FAILURE.

12666 071778 STANICOR KAPPA PACEMAKER CORDIS DOW
TEXT WE HAVE HAD 3 PREMATURE FAILURES OVER A 4 MONTH PERIOD. WE HAVE IMPLANTED 12 PACEMAKERS OF THIS BRAND OVER THE 1977-78 PERIOD, MAKING OUR INCIDENCE OF PREMATURE FAILURE 25%. THE FIRST PACER FAILED THE SAME DAY AS IMPLANT. THE SECOND FAILED 13 MONTHS AFTER IMPLANT. THE THIRD PACER FAILED 2 YEARS AND 5 MONTHS AFTER IMPLANT. (MORE)
FINAL PROBLEM ASSESSMENT:

12666 060578 LAMDA OMNI STANICOR PACEMAKER CORDIS DOW
TEXT A PATIENT EXPERIENCED AN INCIDENT IN A 7-11 STORE. IT IS ALLEGED THAT THE PATIENT UNKNOWINGLY APPROACHED A MICROWAVE OVEN [illegible]

OVER WAS SUBSEQUENTLY TURNED ON AND THE PATIENT SUFFERED SOME TYPE OF HEART DISTRESS. IT IS REPORTED THAT THIS PATIENT HAD PREVIOUSLY SUFFERED A SIMILAR INCIDENT TO THIS WHEN SHE APPROACHED HIS NEIGHBOR USING A POWER CHAIN SAW. (CONDENSED)
FINAL PROBLEM ASSESSMENT: NA

32504 111776 PACEMAKER OMNI-STANICOR R-WAVE INHIBITED CORDIS DOW
TEXT: THE PRODUCT STOPPED WORKING.
FINAL PROBLEM ASSESSMENT: FIRM FEELS PACER WAS AT END OF CREDIT REPLACEMENT POLICY/CAN'T IDENTIFY PROBLEM UNTIL RECEIVE PACER

31692 031576 CARDIAC PACEMAKERS CORDIS MANUFACTURING CO.
TEXT: IN THE PAST 6 MONTHS, WE HAVE HAD MULTIPLE FAILURES OF THE CORDIS PACEMAKER MAINLY DUE TO LEAKAGE OF THE BLOOD AND FLUID INTO THE BLOCK CONNECTING THE PACEMAKER TO THE INTRACARDIAC CATHETER. WE HAVE FOUND PLUG SEALING THE ALLEN SCREW OPENING MIS-SIZED ALLEN SCREWS, VARIOUS ELECTRODE FAILURES. THE CORDIS PACEMAKER PEOPLE ARE WELL AWARE OF THESE DEFICIENCIES. (MORE)
FINAL PROBLEM ASSESSMENT: 1 PACER OUT OF WARRANTY. 2 OPERATING NORMALLY. 1 HAD DEFECTIVE BILATERAL SWITCH. FIRM CONSIDERS RANDOM FAILURES.

31697 051676 PACEMAKER CORDIS
TEXT: POOR PACKAGING. PACEMAKER COMES IN A PLASTIC BOX MADE OF TWO SYMMETRICAL HALVES NOT HINGED AND SIMPLY KEPT TOGETHER BY PAPER TAPE WHEN TAPE IS PEELED OFF TO OPEN BOX, CONTENTS TEND TO FALL OUT OF BOX. IT WOULD BE DESIRABLE TO HAVE THE USUAL ARRANGEMENT OF A BOX WITH A LID. (MORE)
FINAL PROBLEM ASSESSMENT: NEW PACKAGE DEVELOPED PRIOR TO RECEIVING COMPLAINT/CHANGE WAS FOR FINANCIAL REASONS/FIRM FELT USER ERROR CAUSED PACER TO FALL OUT OF PACKAGE

12626 071276 STANICOR PACEMAKER CORDIS
TEXT: THE RATE DECREASED, THE VOLTAGE DROPPED, AND FINALLY THE PACEMAKER WAS EXPLANTED WITHIN 1 1/2 YEARS OF IMPLANTATION.
FINAL PROBLEM ASSESSMENT: 1 PACER FAILED 5 MONTHS AFTER WARRANTY. 1 PACER IMPLANTED AFTER "USE BEFORE" DATE. 1 RANDOM FAILURE.

32462 062176 TEMPORARY PERVENOUS LEAD CORDIS
TEXT: DURING AN EMERGENCY PACEMAKER INSERTION, THE PACEMAKER ELECTRODE WAS INSERTED WRONG END FIRST. THE ENDS LOOK SLIGHTLY DIFFERENT, BUT ARE NOT GROSSLY DIFFERENT. IN AN EMERGENCY SITUATION CAN BE REVERSED. MY SUGGESTION IS TO HAVE THE ENDS BE DIFFERENT COLORS OR TO PACKAGE THE HEAD SO THAT IT CAN ONLY COME OUT OF THE DISPENSER IN ONE DIRECTION, I.E., IT WOULD HAVE TO COME OUT WITH THE INTRODUCING END FIRST. (CONDENSED)
FINAL PROBLEM ASSESSMENT: FIRM STATED AND SHOWED THAT ENDS ARE DIFFERENT BY VISIBLE IDENTIFICATION, BUT AGREED THAT IT DID NOT PREVENT USE OF WRONG END/FIRM HAS REPLACED LEAD WITH A SINGLE UNIT LEAD, WITHOUT USE OF CANNULA WHICH WAS FORMERLY USED TO INTRODUCE LEAD.

12703 071076 OMNI STANICOR PACEMAKER CORDIS
TEXT: COMPLAINANT WAS IN A STORE WHEN ATTENDANT PLACED FOOD IN A MICROWAVE OVEN. COMPLAINANT BEGAN TO FEEL FAINT AND SICK. HE BELIEVES RADIATION FROM MICROWAVE AFFECTED HIS PACEMAKER. COMPLAINANT WAS ADMITTED TO ICU FOR CORONARY MALFUNCTION. UNIT WAS TESTED AND FOUND TO BE IN GOOD CONDITION. (MORE)
FINAL PROBLEM ASSESSMENT: DR. REGARDS OVEN AS VERY LOW POSSIBILITY AS CAUSE FOR PATIENT REACTION. PACEMAKER OPERATING EFFICIENTLY UPON ADMITTANCE TO HOSPITAL.

34758 091779 PACEMAKER CORDIS CORPORATION
TEXT: REPORTER STATES THAT ONE OF HIS PATIENTS HAD A MALFUNCTIONING PULSE GENERATOR DUE TO APPARENT BATTERY DEPLETION. THIS OCCURRED AT SEVEN MONTHS PAST IMPLANTATION AND INDICATES PREMATURE BATTERY FAILURE. THE

PULSE GENERATOR IS BEING RETURNED TO THE MFGR FOR DETAILED ANALYSIS. (SEE FILE)
FINAL PROBLEM ASSESSMENT: FIRM IS AWARE THAT BATTERY DEPLETION CAN OCCUR IN LITHIUM CUPRIC SULFIDE BATTERIES/REGULAR MONITORING OF PACERS IS RECOMMENDED/PT. REFUSED MONITORING, THEREFORE A BATTERY DEPLETION CAUSING 10% DECREASE COULD NOT HAVE BEEN DETECTED.

35270 120579 PACEMAKERS & ELECTRODE LEAD CORDIS
TEXT: THE ELECTRODE LEAD AS IT PLUGS INTO THE PACEMAKER IS DIFFERENT FROM ONE MANUFACTURER TO ANOTHER. IT WOULD MAKE IT MORE CONVENIENT IF THE SAME SIZE CABLE WERE PRODUCED THAT COULD BE USED INTERCHANGEABLE WITH DIFFERENT BRAND PACEMAKERS. ALTHOUGH THERE IS AN ADAPTER KIT AVAILABLE THESE OFTEN RESULT IN MALFUNCTIONS AND ADD AN UNNECESSARY HAZARD. WOULD LIKE TO SEE AN FDA REQUIREMENT FOR A STANDARD ELECTRODE SIZE.
FINAL PROBLEM ASSESSMENT: NA

35271 120579 CARDIAC PACER CORDIS CORPORATION
TEXT: PACEMAKER IMPLANTED 5/25/78, LITHIUM BATTERY POWER. POWER FAILED AND PACEMAKER REMOVED 10/10/79 AT MEDICAL CENTER. ANOTHER LAMBDA(CRD) STANICOR PACER INSTALLED TO REPLACE DEFECTIVE ONE. LITHIUM POWER CELLS SUPPOSED TO HAVE LIFE OF EIGHT PLUS YEARS, BUT THIS ONE FAILED IN 17 MONTHS.
FINAL PROBLEM ASSESSMENT:

35720 012580 PULSE GENERATOR CORDIS CORPORATION
TEXT: EARLY BATTERY DEPLETION OF PACEMAKER. THE FIRST PACEMAKER WAS IMPLANTED 8/31/78 WITH A RATE OF 71.8 BPM AT IMPLANT, THIS PACEMAKER WAS REPLACED ON 11/21/79 WITH A RATE OF 58 BPM. THE SECOND PACEMAKER WHICH WAS COMPLAINED ABOUT WAS IMPLANTED ON 8/16/78 WITH A RATE OF 81.2 BPM AT IMPLANT, THIS PACEMAKER IS TO BE REPLACED ON 1/24/80. THE RATE AS OF THIS DATE IS DECREASED TO 78.7.
FINAL PROBLEM ASSESSMENT:

35552 121779 PACEMAKER CORDIS
TEXT: APPEARS TO BE PREMATURE BATTERY EXHAUSTION, BUT HAVE SEEN SIMILAR COMPLAINTS. THIS MAY BE INDICATIVE OF A TREND.
FINAL PROBLEM ASSESSMENT:

36531 061280 PACEMAKER GENERATOR CORDIS
TEXT: PACEMAKER MALFUNCTIONED PERMANENTLY CAUSING A PRECEPITATION DROP OF THE HEART RATE IN A PATIENT WITH COMPLETE HEART BLOCK. (THIS IS THE SAME PROBLEM THAT REQUIRED A PACEMAKER IN THE BEGINNING).
FINAL PROBLEM ASSESSMENT: FIRMS FINDINGS SHOW THAT PACEMAKER WAS NOT OPERATING WITHIN SPECS. PACEMAKER HAD MALFUNCTIONED PREMATURELY DUE TO MERCURY-ZINC BATTERY DEPLETION AFTER 25 MONTHS.

14117 100280 PACEMAKER CORDIS CORP
TEXT: PATIENT HAD OMNISTANCOR LAMBDA UNIT IMPLANTED WHICH HAS BEEN FUNCTIONING ADEQUATELY. THE HIGH SCHOOL WHERE PATIENT ATTENDS INSTALLED A SENSING DEVICE TO MONITOR UNAPPROVED WITHDRAWAL OF BOOKS FROM THEIR LIBRARY. THIS UNIT, AND IMMEDIATELY HAD A FEELING OF DIZZINESS WITH A FEELING OF OPPRESSION. THIS PERSISTED FOR APPOXIMATELY A DAY TO A DAY AND A HALF. (SEE FILE)
FINAL PROBLEM ASSESSMENT: EMI FM BOOK DETECTOR: INTERACTION OF PACERS & DETECTOR STUDIED IN 1975. EMI OBSERVED. DETECTOR MFR WAS TO PUT WARNING ON THEIR UNITS. USER'S PROBLEM RESOLVED.

37495 120880 CARDIAC PACEMAKER CORDIS CORPORATION
TEXT: CATASTROPHIC PACEMAKER FAILURE WITH NO DETECTABLE OUTPUT & TOTAL LOSS OF EFFECTIVE PACING. PACEMAKER REQUIRED REPLACEMENT. PT AT JEOPARDY FROM AN INADEQUATE HEART RATE W/O PACEMAKER. FAILED AFTER 34 MONTHS POST-IMPLANTATION. UNIT RETURNED TO MANUF FOR EVALUATION. ANALYSIS OF PULSE GENERATOR ATTACHED. (SEE FILE)
FINAL PROBLEM ASSESSMENT: PACEMAKER FAILED: MFR'S INVESTIGATION FOUND PREMATURE

BATTERY DEPLETION AFTER 34 MONTHS. PATIENT HAD NOT BEEN MONITORED REGULARLY (FOR EOL INDICATION).

14655 040761 OMNI-STANICOR CORDIS CORP
TEXT PACEMAKER NOT FUNCTIONING PROPERLY. DOCTOR EXPLANTED THE PACEMAKER
FINAL PROBLEM ASSESSMENT: PACEMAKER NOT FUNCTIONING PROPERLY/PACER SENT TO BAE LAB/LAB VERIFIED LOW OUTPUT UNDER TEST LOAD/PACER DESIGNED FOR 5 YRS LIFE & THIS PACER PROB NOTED 3 YRS, 3 MO AFTER IMPLANT/DOES NOT APPEAR TO BE UNIT FAILURE/DCO RESPONDED TO RPIR.

15210 092481 LAMBDA OMNI-STANICOR PACEMAKER CORDIS CORP
TEXT: PATIENT HAD PACEMAKER IMPLANTED ON 6/25/77. AT THIS TIME SHE WAS INFORMED IT WOULD LAST 8 TO 10 YRS. ON 9/3/81 PACEMAKER FAILED REDUCING HER PULSE FROM 75 TO 45. SHE WAS HOSPITALIZED FOR PACEMAKER REPLACEMENT. HER DOCTOR BELIEVES THE FAILURE TO BE EITHER BATTERY OR LEAK RELATED.
FINAL PROBLEM ASSESSMENT:

15646 042182 PACEMAKER CORDIS
TEXT: DURING REPROGRAMMING OF PACEMAKER, ON PUSHING THE PROGRAMMER AT A RATE OF 70, IT FELL TO 36. IT LOST ITS ABILITY TO SENSE & IT LOST ITS ABILITY TO CAPTURE THE VENTRICLE. UNABLE TO REPROGRAM IT. IT REMAINED AT THAT RATE & WOULD NOT SENSE OR CAPTURE REGARDLESS OF ATTEMPTS TO PROGRAM ITS RATE, OUTPUT, SENSITIVITY, OR MODE DIFFERENTLY. SIMILAR EVENT NOTED IN NEARBY COMMUNITY. MAY REFLECT A DESIGN PROBLEM.
FINAL PROBLEM ASSESSMENT:

36629 062580 BIPOLAR PACEMAKER ELECTRODE 4F., 115 CM.
U.S.C.I. DIV. OF C.R. BARD
TEXT: FAILED TO TRANSMIT IMPULSE. PRODUCT X-RAYED, REVEALS WIRE LOOP INSIDE WIRE JUNCTION COMPONENT.
FINAL PROBLEM ASSESSMENT: XRAY FILM SHOW THAT CATHETER LEAD WAS NOT FULLY INSERTED INTO THE CONNECTOR MAKING IT IMPOSSIBLE TO INSERT FAR ENOUGH TO COMPLETE THE CIRCUIT. ALSO THERE WAS A CUT 13 CM FROM TIP OF CATHETER, SEVERING THE WIRES.

34490 081079 BI-POLAR CARDIAC PACING ELECTRODE
DAIG CORP
TEXT: DEFECTIVE ELECTRODE. APPEARS THAT THE DISTAL LEAD WAS THOUGHT TO BE CRACKED. COULD NOT SENSE PROPERLY AND WAS NOT PACING PROPERLY. THIS DID NOT RESULT IN ANY DAMAGE TO THE PATIENT.
FINAL PROBLEM ASSESSMENT: FIRM UNABLE TO CONFIRM PACEMAKER LEAD FAILURE DUE TO CRACKED ELECTRODE. USER DESTROYED IT. REVIEW OF QA RECORDS AT FIRM SHOWED ELECTRONICS OF EACH LEAD CHECKED PRIOR TO DISTRIBUTION.

36694 080880 LITTLEFORD/SPECTOR INTRODUCER/PACEMAKER
DAIG CORPORATION
TEXT: DURING INSERTION OF A PERMANENT PACEMAKER THE VESSEL DILATOR AND SPLIT SHEATH INTRODUCER WERE PLACED IN THE SUBCLAVIAN VEIN. THERE IS NO TAB OR HOLDING DEVICE ON THE SPLIT SHEATH INTRODUCER. THE SHEATH SLIPPED INTO THE SUBCLAVIAN VEIN & COULD NOT BE RETRIEVED. IT IS NOT RADIOPAQUE, SO IT COULD NOT BE SEEN WITH FLUOROSCOPY. SHEATH WAS FOUND TO BE AROUND THE PACEMAKER WIRE. REMOVAL WAS NOT ATTEMPTED. COMPANY REP WAS PRESENT AND AWARE OF PROBLEM. SHEATH WAS FOUND BY ECHOCARDIOGRAM. (LABEL)
FINAL PROBLEM ASSESSMENT: FIRM COULD NOT RECREATE THE PROBLEM. RETAINED SAMPLE MET ALL SPECS. NO SIMILAR COMPLAINTS. APPEARS TO HAVE BEEN PHYSICIANS ERROR RATHER THAN DEVICE FAILURE.

11417 111076 BIPOLAR PACING CATHETER CABLE EDWARDS LABORATORIES
TEXT: CONNECTING CABLE TOO LONG. WOULD LIKE A SHORTER CABLE TO LESSEN NEED FOR COILING UNDER DRESSING - INCREASES BULK OF DRESSING NEEDED OVER PACEMAKER INSERTION SITE.
FINAL PROBLEM ASSESSMENT:

32096 061878 BALLOON-TYPE CARDIAC PACEMAKER CATHETER
EDWARDS
TEXT: UPON INSERTION I NOTED THE BALLOON WAS DISCOLORED SLIGHTLY. WE HAD DIFFICULTY IN OBTAINING CAPTURE, AND WITH STOPCOCK TURNED OPEN TO AIR, I NOTICED BLOOD RETURNING FROM STOPCOCK SUGGESTING THE BALLOON RUPTURED. UPON TESTING OTHER CATHETERS IN STOCK, 6 IN A ROW RUPTURED. ALL WERE ABOUT 6 MONTHS OLD AND HAD A SLIGHT DISCOLOR TO THEM. COMPANY STATED THEY WERE AWARE OF PROBLEM AND WERE REDESIGNING CATHETER. HOWEVER, THEY DID NOT NOTIFY ANY USERS OF THE PROBLEM. (MORE)
FINAL PROBLEM ASSESSMENT: ACCELERATED DEGRADATION OF THIS CATHETER BALLOON/MFGR. RECALLED LOTS IN QUESTION/I-331-8

13190 061479 PACEMAKER EDWARDS PACEMAKER SYSTEM
TEXT: THE COMPLAINT CONCERNS THE APPARENT MALFUNCTION OF A PACEMAKER. THE COMPLAINANT IS A 49 YEAR OLD FEMALE. THE PACEMAKER WAS IMPLANTED ON 4/21/78 FOLLOWING A MITRAL VALVE INSERTION. ON 10/06/78 THE PACER APPARENTLY MALFUNCTIONED CAUSING AN EMERGENCY HOSPITALIZATION. THE PACER WAS EXPLANTED AND A DIFFERENT MODEL WAS IMPLANTED. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

35826 021180 FLOW DIRECTED PACING CATHETERS EDWARDS LABORATORIES
TEXT: CATHETER IS LISTED BY FRENCH SIZE. IF ATTEMPTING TO INSERT CATHETER THROUGH A PACEMAKER INTRODUCER, YOU MUST USE AN INTRODUCER WHICH IS ONE FRENCH SIZE LARGER, ACCORDING TO THEIR CUSTOMER SERVICE REP. THIS PRODUCT CAN BE ROUTINELY USED IN EMERGENCY PACEMAKER PROCEDURES BECAUSE OF ITS FLOW DIRECTED FEATURE. BY NOT CLEARLY STATING ON THE PACKAGE THAT A LARGER INTRODUCER IS REQUIRED, VALUABLE TIME IS LOST, SIGNIFICANTLY DECREASING THE PATIENT'S CHANCES FOR SURVIVAL.
FINAL PROBLEM ASSESSMENT: COMPLAINT STATED THE FR SIZE OF THE PACING CATHETER MUST BE OF SMALLER SIZE THAN THE INTRODUCER/FIRM IS CHANGING LABELING TO INDICATE INTRODUCER SHOULD BE 1 FR SIZE LARGER/NO SIMILAR COMPLAINTS

38067 041381 SWAN GANZ PACEMAKER CATHETER EDWARDS LABORATORIES
TEXT: PACEMAKER ELECTRODE DISPLACEMENT AFTER 1 OR MORE DAYS. PACEMAKER ELECTRODE FRACTURE IN 1 INSTANCE.
FINAL PROBLEM ASSESSMENT:

10629 043076 BALLECTRODE BIPOLAR PACING KIT ELECTRO CATHETER CORP
TEXT: BROKEN TEMPORARY P ING CATHETER. CONTACT WITH MFG SALES REP. INDICATED FIRM HAD LEAD BREAKAGE PROBLEM WITH EARLY 1975 PRODUCTION.
FINAL PROBLEM ASSESSMENT: 255

10914 071976 CARDIAC PACEMAKER KIT, ADAPTER ELECTRO-CATHETER CORP
TEXT: APPROXIMATELY EIGHT HOURS AFTER INSERTION OF THE PACEMAKER, IT WAS NOTED THAT IT WAS NOT FUNCTIONING AND THE PATIENT HAD REVERTED TO HIS UNDERLYING HEART RHYTHM. A QUICK CHECK REVEALED THAT ONE OF THE SMALL METAL PRONGS WHICH CONNECTS TO THE CONNECTING WIRE ON ONE SIDE AND IS INSERTED INTO THE PACEMAKER BOX, HAD BECOME SEPARATED FROM THE PLASTIC ENCLOSED WIRE OF THE CONNECTING ADAPTER. (MORE)
FINAL PROBLEM ASSESSMENT:

10960 061676 BALECTRODE PACING KIT ELECTRO-CATHETER CORPORATION
TEXT: EXTERNAL TERMINAL CONNECTORS ON PACER CATHETER TIP (AT PACEMAKER CONNECTION SITE) HAVE BROKEN AWAY FROM THE PACEMAKER WIRE AFTER THE WIRE WAS INSERTED INTO A PATIENT, AND AFTER CONNECTION TO PACER MODULE WAS MADE. THIS CAUSED NON-CAPTURE OF THE PACEMAKER. THIS OCCURRED IN FOUR INDIVIDUAL PATIENTS AND WE TESTED APPROXIMATELY SIX OTHER PACER KITS YIELDING THE SAME DEFECT.
FINAL PROBLEM ASSESSMENT:

10960 061676 PACING PROBE CATALOG BBB ELECTRO-CATHETER CORPORATION
TEXT: POSSIBILITY OF A DEFECT THAT MAY CAUSE THE EXTERNAL TERMINALS TO BREAK

AWAY FROM THE CONDUCTING WIRES AS INFORMED BY THE COMPANY IN LETTER OF MAY 25, 1976.
FINAL PROBLEM ASSESSMENT:

11571 121076 CONNECTING ADAPTER/PACEMAKER ELECTRO-CATHETER CORP
TEXT: ON DECEMBER 4, 1976, WE EXPERIENCED A FAILURE TO PACE WHICH WAS DETERMINED TO BE CAUSED BY FAILURE OF THIS PARTICULAR PIECE OF EQUIPMENT (WIRE DISCONNECTED FROM PRONGS). WE HAVE HAD SEVERAL PRIOR FAILURES OF THIS PIECE OF EQUIPMENT. (MORE)
FINAL PROBLEM ASSESSMENT:

11652 022277 TRANSMYOCARDIAL PACING UNIT ELECTRO-CATH
TEXT: MALFUNCTION IN TWO SUCCESSIVE UNITS. (MORE)
FINAL PROBLEM ASSESSMENT:

35012 110179 ELE CATH SEMIFLOATING PACING KIT
ELECTRO CATHETER CORPORATION
TEXT: REPORTER BELIEVES THERE WAS A PROBLEM WITH THE ELECTRICAL CONNECTOR. PACEMAKER DID NOT CAPTURE WITH THE CONNECTOR.
FINAL PROBLEM ASSESSMENT:

35531 122779 ELECATH TRANSTHORACCIC PACING KIT
ELECTRO CATHETER CORP.
TEXT: NO PROBLEMS EXCEPT SHORT EXPIRATION DATE. IT SEEMS IT SHOULD BE MORE THAN 1 YEAR AND ALSO POSSIBLY RE-STERILIZING BY GAS IN HOSPITAL.
FINAL PROBLEM ASSESSMENT: NA

35705 012480 BALECTRODE PACING KIT ELECTRO CATHETER CORP.
TEXT: THE LABELING ON THIS KIT IS VERY POOR. THIS KIT CONTAINS A TRANSVENOUS PACING KIT AND THIS IS NOT CLEARLY STATED. THIS COULD BE CONFUSED WITH A TRANSTHORACTIC PACING KIT.
FINAL PROBLEM ASSESSMENT: COMPLAINT OF POOR LABELING ON PACKAGE OF KIT/FIRM STATES THE INSTRUCTION BOOKLET CLEARLY STATES PRODUCT IS FOR TRANSVENOUS PASSAGE/FIRM BELIEVES LABELING IS ADEQUATE.

37710 020681 TRANSTHORACIC PACING KIT ELECTRO-CATHETER CORP
TEXT: THERE IS A VERY SHORT TIME PERIOD FROM PURCHASE DATE TILL EXPIRATION DATE WITH THIS PRODUCT. CO WILL NOT GIVE A DEFINITIVE ANSWER ABOUT THE USE OF GAS STERILIZATION TO EXTEND THE SHELF LIFE OF THIS KIT.
FINAL PROBLEM ASSESSMENT: SHORT EXP DATE & UNABLE TO GET RESTERILIZATION DIRECTIONS/MFR WILL NOT GIVE HOSPITALS PERMISSION TO RESTERILIZE PRODUCT BECAUSE OF LIABILITY IF IT IS INCORRECTLY DONE.(EXP DATE PRACTICES WERE NOT DISCUSSED)

39534 040882 PACEMAKER KIT SP BALECTRODE PACING KIT
ELECTRO-CATHETER CORP
TEXT: DEFECTIVE BALLOON TIPPED PACEMAKER. BALLOON WOULD NOT WORK/INFLATE. REPORTER HOLDING SAMPLE.
FINAL PROBLEM ASSESSMENT:

11262 101876 PACEMAKER LITHIUM BATTERY INTERMEDICS INC
TEXT: THE PACEMAKER FAILED AFTER ONLY A FEW MONTHS USE. IT ALLEGEDLY WAS THE SECOND PACEMAKER MADE BY INTERMEDICS IMPLANTED IN THIS PATIENT IN LESS THAN ONE YEAR. THE POCKET AT SURGERY WAS FOUND TO BE FILLED WITH RUST-COLORED PURULENT APPEARING MATERIAL. THE PACEMAKER WAS FOUND TO HAVE AN OUTPUT OF 0.2 MA. I WOULD LIKE THIS PACEMAKER EXAMINED AND WILL SEND IT TO WHATEVER AGENCY YOU DESIRE.
FINAL PROBLEM ASSESSMENT:

31355 122277 PACEMAKER/INTERLITH C-MOS INTERMEDICS
TEXT: INHIBITED PACEMAKER DISCHARGE DURING MOVEMENT OF TEST MAGNET OVER PACEMAKER. THIS CHARACTERISTIC NOT DESCRIBED IN PACEMAKER MANUAL. COMPANY NOTIFIED OCTOBER, 1977.
FINAL PROBLEM ASSESSMENT: NA

31379 122777 INTERLITH PACEMAKER INTERMEDICS
TEXT: DEMAND PACER CAN BE COMPLETELY TURNED OFF BY EITHER HORSESHOE OR DOUGHNUT MAGNET IF WAVED OVER THE PACEMAKER. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12431 021578 PACEMAKER INTERMEDICS INC.
TEXT: IN 1973 COMPLAINANT HAD A MEDCOR PACEMAKER IMPLANTED. WHEN PACEMAKER WAS REPLACED DUE TO DEVICE AGE, A INTERMEDICS PACEMAKER WAS IMPLANTED. COMPLAINANT STATES THAT IT MALFUNCTIONED SOON AFTER AND HAD TO BE REPLACED WITH ANOTHER. FEELS GAP'S ARE MOST IMPORTANT IN MANUFACTURER OF ALL PACEMAKERS. (MORE)
FINAL PROBLEM ASSESSMENT:

32172 070578 PACEMAKER INTERMEDICS
TEXT: PACER FAILED 10 MONTHS AFTER INITIAL IMPLANT.
FINAL PROBLEM ASSESSMENT: FIRM TESTING SHOWED ONE CIRCUIT TRANSISTOR FAILED/ONE ADDITIONAL FAILURE NOTED/FIRM FEELS RANDOM FAILURE

13051 040579 PACEMAKER/UNIPOLAR INTERMEDICS
TEXT: THIS SEEMS TO BE A DESIGN PROBLEM. AS THE PATIENT MOVES ARM (AND ARM MUSCLE), THE ARM MUSCLES ELECTRICAL SIGNALS SEEM TO BE "CONFUSING" THE PACEMAKER'S SENSING CAPABILITIES. IN CONDUCTED LAB STUDIES, COMPLAINANT STATES THAT SOME ARM MOVEMENT HAS CAUSED THE PACEMAKER TO CEASE PACING. TESTED ONE OUT OF 12 PACERS.
FINAL PROBLEM ASSESSMENT: NA

35578 010480 PROGRAMMABLE RATE PACEMAKER INTERMEDICS INC.
TEXT: PACEMAKER INSERTED 12/6/79. PATIENT EXPIRED 1/4/80. WAS THIS PACEMAKER FUNCTIONAL?
FINAL PROBLEM ASSESSMENT: FIRM F-U REVEALED LACK OF EVIDENCE TO SUPPORT REPORTERS ALLEGATIONS. END LAB ANALYSIS OF PACER CONFIRMED FIRMS FINDINGS.

13479 013080 PACEMAKER INTERMEDICS, INC.
TEXT: PACEMAKER RELATED DEATH. PATIENT WAS OPERATED ON FOR AORTIC VALVE REPLACEMENT ON 11/6/78. OPERATION MUST HAVE DESTROYED HEART'S CONDUCTION MECHANISM BECAUSE IT WAS NECESSARY TO IMPLANT PACEMAKER. ON 12/30/79 PATIENT COLLAPSED WHILE STANDING IN PARKING LOT AND DIED. PACEMAKER HAD STOPPED PACING.
FINAL PROBLEM ASSESSMENT:

14380 110380 PACEMAKER INTERMEDICS INC
TEXT: POSSIBLE DEATH DUE TO PACEMAKER FAILURE. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

14581 011681 PACEMAKER INTERMEDICS, INC
TEXT: PACEMAKER WAS IMPLANTED ON 10-31-78. ON 12-23-80 PT. BEGAN TO SUFFER PAINS IN HIS CHEST. HE WAS TAKEN TO HOSPITAL AND INFORMED THAT HIS PACEMAKER WAS MALFUNCTIONING. ON 12-23-80 IT WAS EXPLANTED AND A NEW ONE PUT IN.
FINAL PROBLEM ASSESSMENT: FIRM HAS HAD ONLY 5 OTHER CONFIRMED FAILURES TO SENSE OUT OF 31,000 IMPLANTS. FIRM BELIEVES THE REASON FOR THIS FAILURE COULD BE IMPROPER PLACEMENT OF LEAD, DEFECTIVE LEAD OR PATIENT HAD UNUSUAL SENSITIVITY THRESHHOLD.

14636 123180 PACEMAKER INTERMEDICS
TEXT: ETO CONTAMINATION SUSPECTED
FINAL PROBLEM ASSESSMENT: FIRM'S F/U ON ETO AND STERILITY TEST RECORDS FOR THIS SERIAL NUMBER ARE WITHIN SPECIFICATIONS.

36423 070881 CYBERLITH PACEMAKERS INTERMEDICS INC.
TEXT: BROCHURE MENTIONS THAT THIS DEVICE CAN BE STERILIZED IF THE PACKAGING HAS BEEN DAMAGED. THE METHOD MENTIONED USES ETHYLENE OXIDE. SPECIFIC

INSTRUCTIONS WERE REQUESTED FROM THE COMPANY. COMPANY WILL NOT PROVIDE WRITTEN GUIDELINES FOR PROCEDURE.
FINAL PROBLEM ASSESSMENT:

15094 083181 ARCOLITH PULSE GENERATOR INTERMEDICS, INC
TEXT: DOCTOR REPORTS HE HAD TWO OF THESE UNITS FAIL AT 21 MONTHS. HE QUESTIONS THE ADVISORY LETTER THAT WAS SENT OUT BY THE MANUFACTURER. CONCERNING THE PROPHILOTIC REPLACEMENT OF ARCOLITH MODELS 3 & 4 DUE TO BATTERY DEPLETION. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

15169 100781 INTERLITH PACEMAKER INTERMEDICS INC
TEXT: REPORTER STATES, PATIENT, A 54 YR OLD FEMALE DIED WHILE WEARING A PACEMAKER. CAUSE OF DEATH NOT CERTAIN, BUT FEELS PACEMAKER COULD BE THE REASON.
FINAL PROBLEM ASSESSMENT: INTERIM RE POSSIBLE PACER FAILURE: EMD LAB EVALUATION OF SAMPLE DID NOT DEMONSTRATE ABNORMAL PULSE GENERATION BEHAVIOR/

10512 042776 PACEMAKER MEDTRONIC
TEXT: RECENTLY WE HAVE HAD TO CHANGE PACEMAKERS IN 6 PATIENTS BECAUSE OF POSSIBLE COMPONENT FAILURE. 2 INVOLVED MODEL 5950. IN 1 OF THESE THE CO. SAID THERE WAS CONSIDERABLE BATTERY DEPLETION & THE OTHER IS STILL UNDERGOING TESTING. 2 MORE INVOLVED NO L 5944 AND ALSO INVOLVED BATTERY DEPLETION. THERE MAY BE A RELIABILITY PROBLEM ABOVE AND BEYOND THAT ASSOCIATED WITH THE OLDER 5950XYTRON UNITS. POSSIBLY INVOLVING OTHER UNITS. (MORE)
FINAL PROBLEM ASSESSMENT:

10747 061576 PACEMAKER MEDTRONIC INC
TEXT: 6 PACEMAKER FAILURES-- 1) 5P02501--IMPLANTED 7/6/75--EXPLANTED 3/22/76--NO OUTPUT-- 2) 4P04800--IMPLANTED 3/1/75--EXPLANTED 3/31/76--NO OUTPUT-- 3) 5P00196--IMPLANTED7/15/75--EXPLANTED 3/16/76--NO OUTPUT-- 4) 5P06222--IMPLANTED 6/6/75--EXPLANTED 5/3/76--NO OUTPUT-- 5) 4P07233--IMPLANTED 3/7/75--EXPLANTED 5/27/76--PREMATURE BATTERY FAILURE-- 6) 4X02123-- IMPLANTED 4/9/75--EXPLANTED 5/27/76--PREMATURE BATTERY FAILURE.
FINAL PROBLEM ASSESSMENT: ???

10765 062576 PACEMAKER MEDTRONIC INC
TEXT: LEAD OR ELECTRODE ON PACEMAKER BROKE
FINAL PROBLEM ASSESSMENT:

10880 071976 XYTRON PACEMAKER MEDTRONIC INC
TEXT: THE ABOVE IDENTIFIED PULSE GENERATORS APPEARED TO HAVE FAILED SUDDENLY 10-1/4 TO 16-1/4 MONTHS AFTER IMPLANTATION. ALL FOUR UNITS HAVE BEEN RETURNED TO THE COMPANY FOR ANALYSIS AND TWO ARE BELIEVED TO HAVE FAILED BECAUSE OF PROBLEM KNOWN AS "METALLIC MIGRATION".
FINAL PROBLEM ASSESSMENT:

10951 070376 PACEMAKER XYTRON 5950 MEDTRONICS
TEXT: PACEMAKER FAILURE OCCURRED ON JULY 22, 1976. ONCE AGAIN, THIS OCCURRED ABRUPTLY WITHOUT WARNING. THE FAILURES WITH THESE PACEMAKERS HAVE NOT BEEN PREDICTABLE AND THEY OCCUR ALL AT ONCE. IF THE PATIENT HAS NO UNDERLYING RHYTHM, THE PATIENT COULD DIE VERY EASILY. (MORE)
FINAL PROBLEM ASSESSMENT:

10995 081776 PACEMAKER MODEL 5950 MEDTRONIC INC
TEXT: POSSIBLE MALFUNCTIONING PACEMAKER ASSOCIATED WITH DEATH OF 56 YEAR OLD MALE (MORE) (SEE FILE COPY)
FINAL PROBLEM ASSESSMENT:

11152 090176 DEMAND PACEMAKER MEDTRONIC INC
TEXT: DEVICE HAS INSULATION DEFECTS RESULTING IN EXPOSED WIRES WHICH COULD PRESENT A HAZARD TO PATIENT. (MORE)
FINAL PROBLEM ASSESSMENT:

11313 102276 CARDIAC PACEMAKER MEDTRONIC
TEXT: PREMATURE FAILURE OF PACEMAKER WHICH WAS IMPLANTED 6/17/75 AND FAILED 9/2/76. PACER WAS NOT IN GROUP RECENTLY IDENTIFIED BY MEDTRONIC ON THE RECALL. (MORE)
FINAL PROBLEM ASSESSMENT:

30101 041577 EXTERNAL PACEMAKER MEDTRONIC INC
TEXT: A LIGHT TAP ON ANY MEDTRONIC EXTERNAL PACEMAKER CASE (USING A PENCIL OR FINGER) HAD THE SAME EFFECT AS AN INHIBITING R-WAVE. THE PACER SENSED A "BEAT" AND WITHHELD A PULSE. THIS HAPPENED FOR ANY POSITION OF THE INPUT SNESITIVITY SELECTOR EXCEPT ASYNCHRONOUS. A TRAIN OF THESE TAPS PRODUCED LONG SEQUENCES OF INHIBITED PACER OPERATION. (MORE)
FINAL PROBLEM ASSESSMENT:

30334 052377 PACEMAKER MODEL 5942 MEDTRONIC
TEXT: WITH THE SET SCREWS TIGHTENED THE UNIT SHOULD BE OK. MY CONCERN IS THE EASE WITH WHICH THE NEGATIVE LEAD CAN BE APPARENTLY DISENGAGED BY A QUARTER TURN AND THE FACT MY ORIGINAL TESTING (BEFORE ANYTHING WAS TOUCHED ON THE GENERATOR) SHOWED NO SIGNIFICANT OUTPUT AT THE LEAD TERMINAL. I ALSO QUESTION THE SIGNIFICANCE OF THE FLUID IN THE LEAD INSERT. (MORE)
FINAL PROBLEM ASSESSMENT:

12192 050177 MEDTRONIC PACEMAKER MEDTRONIC INC
TEXT: PREMATURE SLOWING OF THE PACEMAKER FROM AN INITIAL RATE OF SEVENTY-ONE AT THE TIME OF IMPLANTATION IN OCTOBER 1976 TO THE PRESENT RATE OF SIXTY-ONE. (MORE)
FINAL PROBLEM ASSESSMENT:

12200 070177 XYTRON PACEMAKER MEDTRONIC INC
TEXT: I HAVE WRITTEN TO FDA IN THE PAST CONCERNING SERIOUS PROBLEMS WITH THE MEDTRONIC XYTRON SERIES MODEL 5950 AND 5951. THERE IS SUDDEN, ABRUPT, NON-PREDICTABLE COMPLETE FAILURE OF THE UNIT. THERE IS ALSO ABRUPT NONPREDICTABLE LOSS OF SENSING OF THES UNITS. MEDTRONIC IS SIMPLY IGNORING SIGNIFICANT NUMBERS OF THESE ACUTE NON-PREDICTABLE FAILURES THAT ARE NOT ON A RECALL LIST WHTH UNITS THAT ARE ONE TO TWO YEARS OF AGE. I BELIEVE THEY ARE HAZARDOUS AND ARE RESPONSIBLE FOR DEATHS. (MORE)
FINAL PROBLEM ASSESSMENT:

30877 060177 MODEL 5880/EXTERNAL DEMAND PACEMAKERS MEDTRONIC INC
TEXT: EXPOSED TERMINALS OF PACEMAKERS. THERE SHOULD BE A COVER DESIGNED TO SLIP OVER THE TERMINAL ENDS ONCE CONNECTED.
FINAL PROBLEM ASSESSMENT: NA

30991 062677 PACEMAKER MODEL 5880A MEDTRONIC INC
TEXT: CHANGED SENSITIVITY CONTROL BUT KEPT THE SAME MODEL NUMBER (5880A). PAGE THREE OF INSTRUCTION MANUAL GIVES UNCLEAR INSTRUCTIONS AND EXPLANATION OF THE SENSITIVITY CONTROL WHICH HAS BEEN CHANGED.
FINAL PROBLEM ASSESSMENT:

31009 062977 TEMPORARY PACEMAKERS MEDTRONIC INC
TEXT: ACCESS TO CHANGING THE BATTERIES INVOLVES REMOVING SMALL SCREWS WITH A SMALL SCREWDRIVER. THE SCREWDRIVER MUST BE KEPT QUICKLY AVAILABLE, WHICH IS BAD. THE SCREWS ARE SO SMALL, THEY ARE EASILY DROPPED. ACCESS TO THE BATTERIES SHOULD BE EASY AND QUICK (WITH THUMB SCREWS). ALSO A SCREWDRIVER MUST BE KEPT STERILE FOR USE DURING SURGICAL PROCEDRUES IN CASE NEEDED.
FINAL PROBLEM ASSESSMENT:

12243 063077 PACEMAKERS MEDTRONIC INC
TEXT: HOSPITAL REPORTS FOUR INSTANCES OF PREMATURE FAILURE OF IMPLANTED XYTRON PACEMAKERS. ALSO COMPLAINTANT REPORTED THE FAILURE OF 26 OF 104

PACEMAKERS IDENTIFIED IN THE MODIFICATIONS OF RECALLS T-138-9-6 AND T-018-7. (MORE)
FINAL PROBLEM ASSESSMENT:

12259 091477 XYTRON PACEMAKER MEDTRONIC
TEXT: FAILURE OF MEDTRONIC XYTRON PACEMAKER IMPLANTED ON 8/7/75, REPLACED ON 8/11/77, WITH NO PACEMAKER FUNCTION ON PACEMAKER ANALYSIS FOLLOWING WITHDRAWAL OF THE PACEMAKER WHICH WAS NOT PRODUCING ANY PACING SPIKES WHILE IMPLANTED IN THE PATIENT AT THAT TIME. PACEMAKER SHOWED NO CURRENT EMINATING FROM THE PACEMAKER, WITH NO PULSE INTERVAL DISCERNABLE, NO RATE DISCERNABLE. (MORE)
FINAL PROBLEM ASSESSMENT: NA

31099 092877 XYTRON CARDIAC PACEMAKER MEDTRONIC INC
TEXT: UNEXPECTED ABRUPT FAILURE OF PACEMAKER. NO OUTPUT. THIS IS A LIFE THREATENING MALFUNCTION IN A PATIENT WHO IS PACEMAKER DEPENDENT. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12276 091677 PACEMAKER MEDTRONIC INC
TEXT: CATASTROPHIC AND UNANTICIPATED FAILURE OF 2 PACEMAKERS, MODEL NUMBER 5915, SERIAL NUMBER 4V00766, 19 MONTHS POST IMPLANT, AND SERIAL NUMBER 4V00744, 16 MONTHS POST IMPLANT. EXAMINATION OF UNITS, WHICH HAVE BEEN RETURNED TO MANUFACTURER, SHOW COMPLETE ABSENCE OF OUTPUT. (MORE)
FINAL PROBLEM ASSESSMENT: NA

13294 101777 PACEMAKER MEDTRONIC INC
TEXT: MEDTRONIC PRODUCED A PACEMAKER WHICH WAS DEFECTIVE IN THAT THE HERMETIC SEAL WAS NOT COMPETENT AND THE PACEMAKERS WERE FAILING AROUND 24 MONTHS. WE HAVE HAD 6 SUCH FAILURES IN OUR PRACTICE IN THE LAST 5 MONTHS. MANUFACTURER KNEW THAT THESE WERE DEFECTIVE BUT FAILED TO NOTIFY US. (MORE)
FINAL PROBLEM ASSESSMENT:

31296 120677 XYTRON MODEL NO. 5950 PACEMAKER MEDTRONIC
TEXT: THESE THREE PACEMAKERS FAILED WITHIN A FEW DAYS OF EACH OTHER AND REQUIRED REPLACEMENT. THESE PACEMAKERS ARE NOT IN THE GROUP WHICH MEDTRONIC HAS RECALLED. THE LOCAL MEDTRONIC REPRESENTATIVE SAYS THAT AS OF AUGUST 31, 1977, THERE HAVE BEEN ONLY 127 REPORTED FAILURES IN 40,000 UNITS WITH THE ABOVE NUMBERS. I FEEL THERE SHOULD BE A CENTRAL AGENCY KEEPING TRACK OF THESE DEVICE FAILURES. (MORE)
FINAL PROBLEM ASSESSMENT: NA

12333 091677 PACEMAKER PULSE GENERATOR VENTRICULAR MEDTRONIC
TEXT: DOCTOR COMPLAINS THAT HE HAS HAD TO REMOVE 5 PACEMAKERS FROM PATIENT'S DUE TO THE FACT THAT THEY FAILED BECAUSE OF NO ELECTRICAL OUTPUT. (MORE)
FINAL PROBLEM ASSESSMENT:

31791 040678 DEMAND PACEMAKER (TEMPORARY) MEDTRONICS, INC.
TEXT: THE 5880A DEMAND PACEMAKER HAS TWO TERMINAL CAPS WHICH SCREW TO TIGHTEN ONTO THE PACING ELECTRODE. THESE CAPS EASILY AND INADVERTENTLY LOCK EITHER OPEN OR CLOSED, NECESSITATING THAT THE UNIT BE RETURNED TO THE FACTORY EACH TIME THIS OCCURS. THE CAPS CAN BE LOCKED WITH JUST MOVEMENT OF THE GENERATOR ITSELF WHEN NOT CONNECTED TO THE PACING ELECTRODE. (MORE)
FINAL PROBLEM ASSESSMENT:

31894 042778 EPICARDIAL PACEMAKER ELECTRODE MEDTRONIC
TEXT: EPICARDIAL LEAD BECAME DISLODGED FROM R VENTRICLE ABOUT 2 HOURS AFTER IMPLANT AND WAS FOUND LYING LOOSE IN PERICARDIAL SPACE AT RE-OPERATION ON APRIL 14, 1978.
FINAL PROBLEM ASSESSMENT:

12545 041078 PACEMAKER MEDTRONIC
TEXT: PACEMAKER WAS IMPLANTED ON 2/14/77 AND HAD TO BE EXPLANTED ON 12/30/77. PACEMAKER FAILURE WAS DIAGNOSED BY PHYSICIAN. DEVICE CARRIED 30 MONTH WARRANTY AND FAILED AFTER 11 MONTHS. MANUFACTURER SAYS UNIT WAS TESTED AND FOUND TO BE OK. (MORE)
FINAL PROBLEM ASSESSMENT: PACER FAILED IN BODY. HOWEVER, WORKED PROPERLY WHEN TESTED AFTER EXPLANTED.

12551 052478 XYTRON PACEMAKER MEDTRONIC
TEXT: COMPLAINANT SENT A LIST OF 11 PATIENTS WHO HAD PACEMAKER FAILURES. (CONDENSED)
FINAL PROBLEM ASSESSMENT:

12576 021078 PACEMAKER MEDTRONIC
TEXT: INTERFERENCE TO AN ELECTRONIC HEART PACEMAKER ALLEGEDLY CAUSED BY A CITIZENS BAND TRANSMITTER. (MORE)
FINAL PROBLEM ASSESSMENT:

12588 062278 XYTRON PACEMAKER MEDTRONIC
TEXT: HIGH FAILURE RATE AMONG WAVE SOLDERED MEDTRONIC XYTRON PACEMAKERS. THE PROBLEM IS NO OUTPUT. MODEL 5951, SERIAL NUMBERS: 5Y13660, 5Y12170. MODEL 5950, SERIAL NUMBERS: 6P07807, 6P06819, 6P08396, 5P27537, 6P0664, 6P18203. (MORE)
FINAL PROBLEM ASSESSMENT: PREMATURE BATTERY FAILURE/FIRM CONTINUOUS MONITORING BUT FEEL RATE OF FAILURE ACCEPTABLE/BMD WILL ALSO MONITOR

32246 071078 SUTURELESS PACING ELECTRODE/PACEMAKER MEDTRONIC
TEXT: PRODUCT WORKED NICELY FOR 6 MONTHS. CARDIOLOGIST THEN NOTED THAT PATIENT WAS NOT PACING PROPERLY. XRAY SHOWED THAT THE SCREW WAS STILL INTACT RADIOGRAPHICALLY. HOWEVER, THE CONNECTION OF THE ELECTRODE TO THE SCREW HAD BECOME DETACHED AND RETRACTED BACK INTO THE GENERATOR POCKET. (CONDENSED)
FINAL PROBLEM ASSESSMENT: MFGR. TESTS CONFIRMS FRACTURE OF PACING LEAD/ONLY 8 REPORTS OF FRACTURES IN 81,000 IMPLANTS.

12655 071178 XYTRON PACER / PACEMAKER MEDTRONIC, INC.
TEXT: DR. HAS COMPILED A LIST OF PACER FAILURES ON UNITS MANUFACTURED AFTER 9/75. 27 OF THESE WERE REPORTS OF NO OUTPUT, PROBABLY DENOTING ABRUPT FAILURE. 18 OTHER CASES WERE LISTED AS PREMATURE WEAR, DENOTING EITHER PREMATURE BATTERY DEPLETION OR OTHER FAILURE BEFORE WARRANTY EXPIRATION.
FINAL PROBLEM ASSESSMENT: PREMATURE BATTERY FAILURE/FIRM CONTINUES MONITORING, BUT FEEL RATE OF FAILURE ACCEPTABLE/BMD WILL ALSO MONITOR

12737 092678 PACEMAKER MEDTRONIC
TEXT: COMPLAINANT IS ALARMED AT WHAT HE CONSIDERS A DRAMATIC INCREASE IN THE RATE OF PREMATURE FAILURES OF MEDTRONICS 5950 PACEMAKERS. THESE HAVE 3 MODES OF FAILURE. LACK OF SENSING. RATE DROP, INDICATING PREMATURE BATTERY DEPLETION. TOTAL PACEMAKER FAILURE WITHIN 24 HOURS FROM RATE DROP. (MORE)
FINAL PROBLEM ASSESSMENT: PREMATURE BATTERY FAILURE/FIRM CONTINUES MONITORING BUT FEEL RATE OF FAILURE ACCEPTABLE/BMD WILL ALSO MONITOR

12800 110778 MEDTRONIC EPICARDIAL PACEMAKER LEAD MEDTRONIC
TEXT: PATIENT DIED OF HEMORRHAGE DUE TO LACERATION OF RIGHT VENTRICLE OF HEART DURING INSERTION OF PACEMAKER AND LEAD. REPORTER STATES THAT THE LABELING INDICATES THAT THE LEAD SHOULD NOT BE USED FOR A THIN WALLED VENTRICLE OR IN CERTAIN OTHER CASES, BUT THERE IS NO SPECIFIC WARNING AS TO ITS USE ON THE RIGHT VENTRICLE. (MORE)
FINAL PROBLEM ASSESSMENT: F/U BY D/C INDICATES THE LABELING AND INSTRUCTIONS WERE SUFFICIENT.

12640 112278 PACEMAKER, CARDIAC, EXTERNAL MEDTRONIC
TEXT: SHORT BATTERY LIFE WHILE IN THE OFF MODE. UNIT DISCHARGES BATTERY TO AN UNUSEABLE STATE ON A PERIOD OF 7 TO 9 WEEKS OF NON-USE WITH ON/OFF SWITCH IN THE OFF POSITION. INSTRUMENT RECEIVED 6/19/78. (CONDENSED)
FINAL PROBLEM ASSESSMENT:

12874 111378 XYTRON PACEMAKERS MEDTRONIC
TEXT: REPORTER STATES THAT HIS FATHER'S FIRST PACEMAKER WAS IMPLANTED ON OR ABOUT 8/2/76. IT BECAME ERRATIC AND WAS EXPLANTED ON 9/17/76, AND A SECOND PACER WAS IMPLANTED. ON 11/30/76, AN ELECTRODE CATHETER FAILED AND THAT WAS REPLACED. THEN ON 6/2/78, THE SECOND PACER FAILED AND A LITHIUM POWERED PULSE GENERATOR WAS IMPLANTED. REPORTER FEELS THAT THE MFGR SHOULD COVER THE COST OF THE VARIOUS EXPENSE CAUSED BY THESE MALFUNCTIONS. (MORE)
FINAL PROBLEM ASSESSMENT: NA

13046 032979 XYTRON PULSE GENERATOR PACEMAKER
MEDTRONIC
TEXT: HOSPITAL STATES THEY ARE FINDING THE FAILURE OF PACEMAKERS MUCH EARLIER THAN HAD BEEN PREDICTED. THE FAILURE IS AT TIMES UNPREDICTABLE AND IF A PATIENT HAS NO UNDERLYING SUSTAINING RHYTHM, THIS MAY BRING ABOUT HIS DEATH BY ELECTRONIC FAILURE. PROBLEM GREATLY INCREASES BETWEEN 24TH AND 29TH MONTH. PROBLEM SEEMS TO BE LOSS OF HERMATICITY OF THE ELECTRONIC ENCLOSURE. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

34112 060779 TEMPTRON DISPOSABLE BIPOLAR LEAD
MEDTRONIC
TEXT: AFTER THE PACING WIRE WAS INSERTED AND IN PROPER POSITION, THERE WAS NO CAPTURE OR SENSING. THE CABLE AND PACEMAKER GENERATOR WERE FUNCTIONING EFFECTIVELY AFTER A DIFFERENT LEAD WIRE WAS INSERTED. THERE WAS NO OBVIOUS DEFECT TO THE LEAD WIRE SO NO EXPLANATION FOR ITS FAILURE WAS DETECTED.
FINAL PROBLEM ASSESSMENT:

13351 011879 PACEMAKER MEDTRONIC INC
TEXT: THREE PACEMAKERS IMPLANTED WITHIN A PERIOD OF 11 MONTHS. THE FIRST UNIT WAS IMPLANTED ON 11/14/77 AND 2 MONTHS LATER THE ELECTRODE LEAD JUMPED OUT OF THE HEART. ON 1/30/78 RECEIVED SECOND UNIT AND LEADS. IN 10/78 THE TWO ELECTRODE LEADS CORRODED. THE LEADS WERE CAPPED AND A THIRD UNIT WAS IMPLANTED. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

13376 101679 PACEMAKER GENERATOR MEDTRONIC INC.
TEXT: WE HAVE JUST COMPLETED THE MAJOR PORTION OF A CLINICAL REVIEW OF THE GENERATOR (BATTERY AND/OR ELECTRONIC) END-OF-LIFE CHARACTERISTICS OF THE 5950 AND 5951 FAMILY OF PACERS. AS YOU WILL REMEMBER, THESE UNITS WERE THE SUBJECT OF A NUMBER OF RECALLS THERE APPEARS TO BE NO CHARACTERISTIC DIFFERENCE BETWEEN THE PERFORMANCE OF THE 5950 AND THE 5951. OF THE 50 UNITS WHICH FAILED, 25 WERE OF EACH TYPE. THEY WERE ALSO DISTRIBUTED AMONG THE VARIOUS FAILURE CATEGORIES IN A UNIFORM MANNER. (SEE FILE
FINAL PROBLEM ASSESSMENT:

13584 101579 PACEMAKER MEDTRONIC INC.
TEXT: PACEMAKER WAS IMPLANTED ON 10/23/79. THE PACEMAKER FAILED IN 5/79.
FINAL PROBLEM ASSESSMENT:

35076 110979 TEMPORARY PACEMAKER CATHETER KIT
MEDTRONIC
TEXT: EVEN WHEN THE CATHETER HAS BEEN USED ACCORDING TO DIRECTIONS, THERE HAVE BEEN TIMES WHEN THE PULSE GENERATOR HAS FAILED TO SENSE THE HEART BEAT THEREFORE, FAILING TO PACE THE HEART. THIS HAS BEEN OBSERVED BY SEVERAL OTHER PHYSICIANS. THE MFGR'S. REP. INDICATED THAT 1 EVALUATION

OF THE PRODUCT SHOWED EXCESSIVE AMOUNTS OF BLOOD IN THE BOX THAT ATTACHES THE PACEMAKER CATHETER WIRE TO THE PULSE GENERATOR. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

35266 120579 PACEMAKERS AND ELECTRODE LEAD MEDTRONIC
TEXT: THE ELECTRODE LEAD AS IT PLUGS INTO PACEMAKER IS DIFFERENT FROM ONE MFGR'R. TO ANOTHER. IT WOULD MAKE IT MORE CONVENIENT IF THE SAME SIZE CABLE WERE PRODUCED THAT COULD BE USED INTERCHANGEABLE WITH DIFFERENT BRAND PACEMAKERS. MUST KEEP A LARGE STOCK OF PACEMAKERS WHICH DO HAVE A SHORT SHELF-LIFE. ALTHOUGH THERE IS AN ADAPTER KIT, THESE OFTEN RESULT IN MALFUNCTIONS AND UNNECESSARY HAZARD. WOULD LIKE TO SEE AN FDA REQUIREMENT FOR A STANDARD ELECTRODE SIZE.
FINAL PROBLEM ASSESSMENT: NA

35496 122179 PACEMAKER MEDTRONIC INC.
TEXT: THE PACEMAKER WAS IMPLANTED APPROXIMATELY AUGUST '79. THE PATIENT SUDDENLY DIED WITH NO APPARENT CAUSE. PACEMAKER WAS REMOVED AT TIME OF AUTOPSY. INTERNS REPORTED NO IMPULSE AT TIME OF DEATH.
FINAL PROBLEM ASSESSMENT: NA

13441 120779 PACEMAKER MEDTRONIC
TEXT: A LADY IN A SUPERMARKET IN NEW MEXICO WAS BEING CHECKED-OUT WHEN SHE BEGAN TO FEEL FAINT, TINGLY, AND DIZZY. WHEN SHE WALKED OUTSIDE, SHE FELT BETTER. AFTER A FEW MINUTES OF THOUGHT, SHE WALKED BACK INTO THE SUPERMARKET AND STOOD BY THE CHECK-OUT COUNTER. AGAIN SHE HAD THE SAME FEELING OF FAINTING, TINGLING & DIZZINESS. SHE REPORTED THIS TO THE NEW MEXICO ENVIRONMENTAL IMPROVEMENT AGENCY (EIA).
FINAL PROBLEM ASSESSMENT:

36000 031780 DEMAND PACEMAKER/PACING WIRE MEDTRONIC
TEXT: WHEN PACING WIRES ARE PLACED INTO THE POSITIVE AND NEGATIVE TERMINALS AT THE TOP OF THE PACEMAKER, MANY TIMES THE TERMINALS JAM UP. THEN CANNOT REMOVE THE PACING WIRES FROM THE PACEMAKER.
FINAL PROBLEM ASSESSMENT:

13614 032480 XYTRON 11 PACEMKER MEDTRONIC
TEXT: PHYSICIAN MADE A STUDY OF 237 UNRECALLED PACEMAKERS. THE BREAKDOWN ON THESE UNITS AS OF 1/80 WAS: TOTAL IMPLANTED, 237. REMOVED FROM RISK, 159. PATIENT DEATH, 29 (CAUSE NOT KNOWN). PATIENT LOST TO FOLLOW-UP, 68. PROPHYLACTIC REPLACEMENTS, 31. GENERATOR FAILURES, 31. NATURE OF FAILURE: 19% NO-OUTPUT. 29% GROSS RATE DECLINE. 52% NORMAL DECLINE. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

13628 041480 PACEMAKER/MODEL 5986 MEDTRONIC
TEXT: LEAD PUNCTURED MYOCARDIUM WHILE ATTEMPTING INSERTION. PATIENT APPARENTLY SUFFERED NO INJURY.13632
FINAL PROBLEM ASSESSMENT: NA

13672 040180 BIPOLAR PACEMAKER CATHETER MEDTRONIC
TEXT: WRONG SIZE CATHETER INTRODUCER WAS SUPPLIED. THE INTRODUCERS WERE TOO SMALL TO ALLOW THE CATHETER TO PASS THROUGH THEM. THE DIAMETER OF THE CATHETER WAS 5 FRENCH, WHILE THE DIAMETER OF THE INTRODUCERS WAS 4 FRENCH. IF THE INTRODUCER IS TOO SMALL TO ALLOW THE CATHETER TO BE INSERTED, VALUABLE TIME MAY BE LOST IN GETTING EITHER A LARGER INTRODUCER OR A SMALLER CATHETER. (SEE FILE)
FINAL PROBLEM ASSESSMENT: NA

13754 011280 LITHIUM BIPOLAR PACEMAKER MEDTRONIC, INC.
TEXT: COMPLAINANT STATES THAT THE AUTOMATIC CRUISE CONTROL IN HIS AUTOMOBILE CAUSES HIS PACEMAKER TO FUNCTION ERRATICALLY.
FINAL PROBLEM ASSESSMENT:

37605 011581 PACEMAKER PATIENT CABLE MEDTRONICS
TEXT: CABLE CONNECTOR THAT PLUGS INTO PACEMAKER CONTAINS AN INTERNAL STRIP OF 1/16" THICK CIRCUIT BOARD MATERIAL THAT SUPPORTS THE CONNECTOR/S PINS & ACTS AS A STRAIN RELIEF FOR THE CABLE. BECAUSE OF A HOLE IN THE CENTER OF THE BOARD, IT IS VERY FRAGILE & EASILY BROKEN WHEN CONNECTOR IS BEING UNPLUGGED. SUBSEQUENT USE, CAUSING FLEXING OF THE BOARD EDGES, COULD CREATE POTENTIAL HAZARD OF BREAKING OF SMALL WIRES RUNNING THROUGH THE BOARD. INSPECTION OF 35 PACER CABLES REVEALED 75% BROKEN.
FINAL PROBLEM ASSESSMENT: FIRM IS STRENGTHENING FIBER BOARD IN CONNECTOR BLOCK TO PREVENT CABLE CONNECTORS FROM BREAKING. MAY REVISE LABELING INSTRUCTING ABOUT PROPER USE OF CONNECTORS DURING CABLE INSERTION/REMOVAL. MFG BELIEVES IMPROPER HANDLING /OPERATION.

37606 011581 DEMAND PULSE GENERATOR/PACEMAKER
MEDTRONICS
TEXT: THE WORKING CLEARANCE BETWEEN THE SLIDING PROTECTIVE COVER AND THE PACEMAKER CONTROL KNOBS IS TOO MINIMAL. ANY SLIGHT DISTORTION OF THE PLASTIC COVER PERMITS THE LEADING EDGE TO THE COVER TO IMPINGE ON THE PACEMAKER CONTROLS BEING CHANGED INADVERTENTLY.
FINAL PROBLEM ASSESSMENT: RPT THAT SLIDING PROTECTIVE COVER INTERFERED W/KNOB SETTINGS WHERE COVER CLOSED NOT CONFIRMED. MFG REC'D NO SIMILAR REPORTS. STATED ONLY COULD OCCUR IF WARPED OR OFF TRAC. FIRM INCREASED CLEARANCE BY .0071 OF AN INCH.

14540 012781 PACEMAKER MEDTRONIC INC.
TEXT: PACEMAKER WAS IMPLANTED IN 1977 ONTO EXISTING EPICORDIAL WIRE PLUG IN DIFFERENT ELECTRODES. PRESENTED TO DOCTOR ON 10/17/80 WITH HEART RATE OF 114, NON SENSING, FULL CAPTURE, AN APPARENT "RUN AWAY". UNIT SENT TO MFGR.
FINAL PROBLEM ASSESSMENT:

15011 061681 WAVE COUPLED SEQUENTIAL PACER MEDTRONIC, INC
TEXT: THIS EXTERNAL PACEMAKER IS ADVERSELY EFFECTED BY ELECTRO-CAUTERY SURGERY. WHEN CAUTERY IS USED UNIT WILL FAIL TO PACE. IT RECOVERS WHEN CAUTERY IS SHUT OFF. INTRA-AORTIC BALLOON PUMP TRIGGERS IN SYSTEMIC BLOOD PRESSURE. HOSPITAL NO 14.
FINAL PROBLEM ASSESSMENT: REPORT STATES THAT PACER WILL NOT PACE WHEN ELECTRO-CAUTERY UNIT IS OPERATING. UNIT INSPECTED/REPAIRED. PACER INDICATOR DIAL NEEDLE MALFUNCTIONING. PROD. LAST MFGRD '76, LAST SOLD '79. NOT HANDLED AS CMPLNT AS REPAIR.

15114 072181 PACEMAKER, EXTERNAL MEDTRONIC INC
TEXT: THE VENTRICULAR SENSITIVITY PORTION OF CONTROLS FAILED TO FUNCTION, PREVENTING THE VENTRICULAR PACING IMPULSE FROM BEING FIRED BY THE PACEMAKER. THIS MAY RELATE TO A POTENTIAL CONTROL/HUMAN FACTOR PROBLEM.
FINAL PROBLEM ASSESSMENT: REPORTER SENT UNIT TO FIRM WITHOUT ANY CMPLT. FIRM SERVICED, REPAIRED AND RETURNED PACER TO REPORTER. ORIGINAL REPORT TO USP STATED EXTERNAL PACER FAILED TO FUNCTION IN VENTRICULAR PORTION OF CONTROLS.

15112 072181 DEMAND PACEMAKER MEDTRONIC INC
TEXT: DEMAND PACING COMPONENT OF PACEMAKER FAILED TO FUNCTION. FAILURE OCCURRED DURING RESUSCITATION ATTEMPT, COMPLICATING THERAPY, AND MAY HAVE BEEN A CONTRIBUTING FACTOR IN THE PATIENT'S DEATH (CANNOT BE DETERMINED DIRECTLY).
FINAL PROBLEM ASSESSMENT: USER BATTERY WAS PLACED IN UNIT WITH INCORRECT POLARITY RESULTING IN DEMAND PACING FAILURE.

15108 061581 PACEMAKER/EXTERNAL PROGRAMABLE MEDTRONIC INC
TEXT: WEAK BATTERY. PATIENT SUFFERED CARDIAC ARREST WHEN DEVICE FAILED TO CAPTURE HEART RATE, THOUGH PACING SPIKE WAS APPARENT ON MONITOR. THE INSTRUCTION MANUAL WHICH IS TOO BULKY TO BE KEPT WITH DEVICE RECOMMENDS BATTERY BE CHARGED FOR EACH PATIENT, BUT THIS IS NOT MARKED ON THE DEVICE ITSELF.

FINAL PROBLEM ASSESSMENT: FIRM REC'D NO SIMILAR CMPLTS STATING THAT PACER SHOULD BE LABELED THAT BATTERY MUST BE CHANGED FOR EACH PT. BATTERY OPERATES FOR ABOUT 500 HRS. REPORTER STATES THIS INFO CONTAINED IN 'EULAY' MANUAL. FIRM DID'NT RECEIVE CMPLT.

15162 081281 PACEMAKER MEDTRONIC INC
TEXT: REPORTER STATES UNIT FAILS TO PACE WHEN THE ELECTROCAUTERY IS USED (ENI PROBLEM) AND MUST BE TURNED ON AND OFF SEVERAL TIMES IN ORDER TO GET THE UNIT TO RESUME PACING. ALSO UNIT FAILED TO PACE ARTERIALLY. POTENTIAL TO CAUSE SEVERE HYPOTENSION.
FINAL PROBLEM ASSESSMENT: FIRM HAD NOT REC'D UNIT FOR M15162 OR M15011 FOR REPAIR: HAD NO KNOWLEDGE OF COMP'T ABOUT PACERS' FAILURE TO PACE WHEN ELECTRO CAUTERY USED. THESE UNIT WERE IN 1976, LAST SOLD IN '79.

38663 110981 VENTRICULAR INHIBITED DEMAND PACEMAKER MEDTRONIC INC
TEXT: PACEMAKER ELECTRODES CONNECT TO THE GENERATOR PACK VIA A SPRING MECHANISM. PT IS ABLE TO INADVERTENTLY DISCONNECT THE ELECTRODE FROM THE GENERATOR IF THE GENERATOR IS IN THE BED WITH THE PT. ALSO ABLE TO DISCONNECT BY PUSHING ON THE SPRING MECHANISM EVEN THOUGH THE FIRM PROVIDES A PROTECTIVE LEATHER CASE. THIS RESULTS IN TEMPORARY LOSS OF PACING, POSING A POTENTIALLY LETHAL PROBLEM IF NOT DETECTED QUICKLY.
FINAL PROBLEM ASSESSMENT: FIRM AWARE THAT PT COULD INADVERTENTLY DISCONNECT ELECTRODE/GENERATOR PROVIDES INSTRUCTIONS IN LABELING THAT WARN USER TO ATTACH GENERATOR DIRECTLY TO PTS ARM/ACCESSORIES TO FACILITATE CONNECTION ARE ALSO PROVIDED/NO OTHER CMPLTS

39270 021982 TEMPORARY BIPOLAR LEAD CONNECTOR MEDTRONIC INC
TEXT: THERE IS A BUTTON ON THE WHITE CONNECTION SITE WITH AN ELEVATED RIDGE HALF WAY AROUND IT, PROBABLY A SAFETY FEATURE. UNFORTUNATELY, HAVE FOUND THAT THE SAFETY FEATURE IS INADEQUATE IN PREVENTING INADVERTENT RELEASE OF THE PACING WIRE FROM THE CONNECTION SITE. ELDERLY PT WENT INTO SLOW VENTRICULAR RHYTHM WITH COMPLETE AV HEART BLOCK UPON DISCONNECTION. SUGGEST RIDGE AROUND BUTTON COMPLETELY ENCIRCLE THE BUTTON TO AVOID THIS PROBLEM.
FINAL PROBLEM ASSESSMENT:

15465 022382 PACEMAKER INTERMEDICS
TEXT: PACEMAKER IMPLANTED EARLY NOV 81. FEW WEEKS AFTER, PT EXPERIENCED SEVERE PAIN IN LEFT CHEST & COUGHING CLOTS. HOSPITALIZED FOR SEPTICEMIA. PACEMAKER EXPLANTED & HOSP DETERMINED INFECTION AT THE TIP OF THE PACEMAKER. PT REQUESTING INVESTIGATION. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

15462 020882 PACEMAKER/ATRIAL SYN VENTRICULAR MEDTRONIC
TEXT: PT EXPERIENCED SYNCOPAL EPISODES. HAD PACEMAKER CHECKED & IT WAS FINE. FIRM NOTIFIED THAT PROBLEMS WITH THE SOLDER JOINT COULD RESULT IN SUDDEN LOSS OF OUTPUT OF THE PACEMAKER. DECIDED TO EXPLANT PACEMAKER. EXPERIENCED ANOTHER EPISODE OF LIGHTHEADEDNESS & IT WAS FOUND THAT PT HAD BRADYCARDIA & COMPLETE HEART BLOCK W/NO PACER FUNCTION. DEVICE EXHIBITS INTERMITTENT ELECTRONIC FAILURE & IS UNACCEPTABLE RISK. FIRM SHOULD REPLACE ALL. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

15529 030582 PACEMAKER LEAD MEDTRONIC INC
TEXT: APPARENT LEAD MALFUNCTION. PACEMAKER ARTIFACTS NOTED ON SEVERAL OCCASIONS. LEAD ANALYSIS REVEALED AN UNSTABLE THRESHOLD. BOTH LEAD CONNECTOR BOOTS ON THE PULSE GENERATOR WERE COMPLETELY FILLED WITH BLOOD. EXPLANTED 2 TIMES & REPAIRED. MALFUNCTIONING LEAD SENT TO FIRM FOR EVALUATION.
FINAL PROBLEM ASSESSMENT:

15588 042182 PERMANENT PACEMAKER MEDTRONIC
TEXT: PACEMAKER IMPLANTED 2/1/80. EXPLANTED 4/8/82 DUE TO SIGNS OF BATTERY DEPLETION AT 26 MONTHS POST IMPLANT. THIS IS PREMATURE FAILURE AS FIRM PREDICTED PACEMAKER WOULD LAST 42 MONTHS. PRODUCT RETURNED TO FIRM FOR ANALYSIS. (SEE FILE)
FINAL PROBLEM ASSESSMENT:

15682 050382 PULSE GENERATOR & LEAD MEDTRONIC
TEXT: FAILURE OF PACER OR LEAD LESS THAN 1 YR AFTER IMPLANT. PACER IMPLANTED 3/81. SYMPTOMS BEGAN EARLY 1/82. HOLTER SHOWED LAPSES & INTERMITTENT FAILURE. PACER EXPLANTED & NO PROBLEMS FOUND. REIMPLANTED & PROBLEMS CONTINUED. SUSPECTED LOOSE LEAD CONNECTION. REPLACED W/NEW LEAD & PACER FROM DIFFERENT FIRM. OLD PACER SENT TO FIRM FOR ANALYSIS.
FINAL PROBLEM ASSESSMENT:

15700 042082 PACEMAKER LEAD MEDTRONIC INC
TEXT: INSULATION DEFECT BETWEEN THE 2 CONDUCTOR COILS. WHEN ATTEMPTING TO WITHDRAW THE LEAD FOR ANALYSIS, THE LEAD STRETCHED & THE PROXIMAL RING ELECTRODE PULLED AWAY FROM THE DISTAL ELECTRODE & THERE WAS A SIGN.FICANT SEPARATION BETWEEN THE 2. ALSO UNABLE TO TOTALLY WITHDRAW THE ELECTRODE, THE TIP BEING ANCHORED INTO PLACE. FORCED TO SEVERE & LEAVE THE TIP OF THE LEAD.
FINAL PROBLEM ASSESSMENT:

15726 041382 PACEMAKER LEAD MEDTRONIC INC
TEXT: FAILURE OF THE PERMANENT PACEMAKER LEAD. INSULATING MATERIAL APPEARS TO BE THE SOURCE OF THE FAILURE. POLYURETHANE DEGRADATION. LEAD WAS FOUND TO HAVE RESISTANCES THAT VARIED SUGGESTIVE OF INSULATION BREAK. WHEN THE LEAD WAS TUGGED AT, THE ENTIRE LEAD TUBING SEPARATED FROM THE PRIMARY CONDUCTION COIL. SEVERAL AREAS ALONG THE LEAD SHOWED CRACKS IN THE POLYMER. CAUSE OF THE LEAD FAILURE.
FINAL PROBLEM ASSESSMENT:

13408 101779 SELF CHECK PULSERATE MONITOR PACEMAKER SERVICES, INC.
TEXT: REPORTER FEELS THIS DEVICE IS IRRATIONAL AND WOULD ALARM PACEMAKER PATIENTS THAT THEIR PACEMAKER WAS NOT WORKING WHEN IT WAS IN THE STANDBY MODE. FEELS IT SHOULD BE A RX DEVICE AND NOT SOLD OTC.
FINAL PROBLEM ASSESSMENT:

14228 111080 RECHARGEABLE PACEMAKER PACESETTER SYSTEMS, INC.
TEXT: AWARE OF 3 EPISODES OF FAILURE. RELIABLE PATIENTS REPORTED NO SENSING OR PACING-REPLACED RECHARGING UNITS, STILL NOT WORKING. WHILE ON RECHARGER THE PACER WORKS BUT WHEN REMOVED IT CEASES AFTER 1 OR 2 BEATS. THERE APPEARS TO BE FLUID UNDER THE SILASTIC COVER. 2 PACERS SENT TO FIRM AND FIRM RESPONDED UNITS WERE OUT OF SPECS. UNITS ARE WARRENTED FOR 5 YRS. MD HAS 1 PACER AVAILABLE FOR TESTING.
FINAL PROBLEM ASSESSMENT: FIRM HAD 10 SIMILAR REPORTS OF BATTERY FAILURES. FIRM DISCONTINUED PRODUCTION IN JULY '76. DEFICIENCIES NOTED IN COMPLAINT HANDLING AND FAILURE ANALYSIS.

11667 022477 LITHIUM PACEMAKER PLASTRON
TEXT: PACEMAKER IMPLANTED SIX MONTHS AGO. PACEMAKER SURGICALLY REMOVED AND WHEN TESTED IT HAD NO OUTPUT. THERE WAS A FINE WHITISH POWDER SURROUNDING THE UNIT JUST INSIDE THE PLASTIC CASING, APPARENTLY LITHIUM. (MORE)
FINAL PROBLEM ASSESSMENT:

12565 050576 CASCADE II HUMIDIFIER HEATER BENNETT
TEXT: AFTER ROUTINE CLINICAL USE, THE TEMP. PROBE LINE OR SOME ASPECT OF THE HEATER DEVELOPS A SPURIOUS ELECTRICAL SIGNAL THAT TODAY IN OUR ICU, INTERFERED WITH A HEART PACEMAKER ON A NEWLY ARRIVED POST-OP OPEN HEART PATIENT. WE HAD TO DISCONNECT THE TEMP. PROBE LINE TO GET THE PACEMAKER TO OPERATE. ALSO, IN THE PAST, THE CASCADE II HAS INTERFERED WITH MONITORING EQUIPMENT IN THE ICU'S.

FINAL PROBLEM ASSESSMENT: CAUSED ELEC. INTERFERENCE WITH CARDIAC MONITOR AND MAY INHIBIT PACEMAKER/DESIGN FLAW IN TEMP. SENSING PROBE/FIRM IN PROCESS OF DESIGNING A RETROFIT

12533 020378 CARDIAC IMPLANTABLE PACEMAKER SIEMENS-ELEMA
TEXT: COMPANY HAS EXPERIENCED 2 FAILURES OF PACEMAKERS IMPLANTED IN THE U.S. IN THE SAME PATIENT, DUE TO A LOSS OF SENSING CAUSED BY A DESIGN DEFECT. AT LEAST 6 PACERS ARE STILL IMPLANTED IN THE U.S. THAT MAY HAVE SAME DEFECT. (MORE)
FINAL PROBLEM ASSESSMENT: MANUFACTURER HAS IMPROVED PRINTED CIRCUIT BOARD. THIS MADE THE PACEMAKER SENSITIVE TO A BROADER RANGE OF ECG SIGNALS WHICH HAS CORRECTED THE PROBLEM.

15681 021077 CIRCULATORY ASSIST SYSTEM SMEC INC
TEXT: DEATHS REPORTED IN FEB 77 DUE TO FAILURE OF BALLOON ADAPTER IN CIRCULATORY ASSIST SYSTEM. ADAPTER/CONSOLE SEPARATED & CAUSED MACHINE TO REVERSE PHASE AND BE OUT OF PROPER SYNC.
FINAL PROBLEM ASSESSMENT: FIRM PROVIDED NO INSTRUCTIONS RE HAZARD OF DISCONNECTING BALLOON ADAPTER FROM CONSOLE & SUBSEQUENT PUMPING OF BALLOON IN A 180 DEGREE PHASE REVERSAL. MGT REFUSED FDA TO DISCUSS REDESIGN OF EQUIPMENT.

12411 011178 PACEMAKER/140 PACER TELETRONICS
TEXT: FDA HAS LEARNED THAT AT LEAST ONE PACEMAKER MANUFACTURER IS EXPERIENCING ELECTROLYTE LEAKAGE FROM THE SAFT LITHIUM SILVER CHROMATE CELLS WHICH HAS RESULTED IN SHORTING OUT THE CIRCUIT IN A UNDETERMINED NUMBERS OF PACERS. (MORE)
FINAL PROBLEM ASSESSMENT:

14015 102380 EVEREADY MURCURY BATTERY UNION CARBIDE CORP.
TEXT: 9 VOLT BATTERY USED IN VARIOUS MEDICAL ELECTRONICS, ALSO USED IN EXTERNAL PACEMAKERS. COMPLAINANT STATES IN BATCH 225, 61 BATTERIES LEAKING AND CORRODING ON THE NEGATIVE TERMINAL.
FINAL PROBLEM ASSESSMENT:

35183 112679 BIPOLAR PACING ELECTRODE USCI CARDIOLOGY & RADIOLOGY PRODUCT
TEXT: THE PROBLEMS ARE 2-FOLD. A MFGR'NG. DEFECT. OF THE 2 SECURING SCREWS THE 2ND TO COME IN CONTACT WITH THE ELECTRODE MUST BE BACKED OFF MORE THAN THE 1ST IN ORDER TO ALLOW FOR COMPLETE PASSAGE OF THE ELECTRODE AS IT IS BEING INSERTED INTO THE CONNECTOR. IF BOTH SCREWS ARE LOOSENED EQUALLY, ELECTRODE WILL BUTTRESS UP AGAINST THE 2ND SCREW AND WHEN TIGHTENED DOWN, WILL NOT MAKE ELECTRICAL CONTACT. THE 2ND PROBLEM IS THAT OF ENGINEERING DESIGN. (SEE FILE)
FINAL PROBLEM ASSESSMENT: FDA FOUND NO SIMILAR REPORTS OF POOR ELECTRICAL CONTACT. FIRM TESTED RETURNED UNIT AND FOUND WITHIN SPECS AND WORKING PROPERLY. FIRM FEELS PROBLEM OF TECHNIQUE. WILL REVISE LABELING TO DETAIL PROPER TECHNIQUE.

37405 111080 SPECIAL CARE ELECTRODE USCI
TEXT: ENDS OF ELECTRODE CATHETER ARE OF SAME CALIBER & ONLY DESIGNATED BY POORLY VISIBLE COLOR CODE, ALLOWING EASY INADVERTENT INSERTION OF WRONG END OF ELECTRODE INTO PT. PACEMAKER END OF ELECTRODE SHOULD HAVE A DIFFERENT SHAPE WHICH WOULD PREVENT ITS PASSAGE THROUGH PLACEMENT CANNULA.
FINAL PROBLEM ASSESSMENT: FIRM BELIEVES THAT COLOR CODING IDENTIFIERS ARE ADEQUATE TO DIFFERENTIATE PROXIMAL & DISTAL ENDS. DIRECTIONS FOR USE ARE EXPLICIT. NO SIMILAR COMPLAINTS.

10860 070276 PACEMAKER UNKNOWN
TEXT: PACEMAKER IMPLANTED 5/75. HAD TO BE REMOVED WITHIN 10 MONTHS. SHE FEELS SHE WAS UNABLE TO FUNCTION IN HER EVERYDAY ACTIVITIES BECAUSE SHE FELT ILL DURING THAT PERIOD. WITH NEW PACEMAKER IMPLANT, SHE FEELS SHE IS ABLE TO FUNCTION NORMALLY.
FINAL PROBLEM ASSESSMENT:

14099 060479 PACEMAKERS VARIOUS
TEXT: IT WOULD SEEM THAT A UNIVERSAL ADAPTER FOR ALL PACEMAKER LEADS TO BATTERIES SHOULD BE ADAPTED SO THAT PACEMAKER BATTERIES CAN BE INTERCHANGED AND SO THAT SILASTIC SLEEVES DO NOT HAVE TO BE PLACED OVER THE ENDS OF BIPOLAR LEADS TO ADAPT THEM TO UNIPOLAR LEADS. THIS IS UNNECESSARILY CONFUSING. IT MAKES FOR PROBLEMS IN TERMS OF ADAPTING FROM PACEMAKER TO PACEMAKER AND I FEEL IT IS UNNECESSARY AND THAT STANDARDIZATION SHOULD BE CARRIED OUT.
FINAL PROBLEM ASSESSMENT: NA

14504 123180 PACEMAKERS VITATRON MEDICAL INC
TEXT: UNITS FITTED WITH THE "SPECIAL CONNECTION" WHICH ALLOWS THE USE OF MEDTRONIC AND CORDIS PACING LEADS/ CORROSION AT THE CONNECTION SITE REDUCES THE AMPLITUDE AND CHANGES THE PULSE SHAPE CAUSING LOSS OF CAPTURE AND FINALLY NO OUTPUT. THIS FAULT IS TIME DEPENDENT. IT ALSO DEPENDS TO SOME EXTENT ON THE CARE WITH WHICH THE CONNECTION WAS MADE AT IMPLANTATION.
FINAL PROBLEM ASSESSMENT: NA

APPENDIX J

From: MIN (FDA054) Posted: Tue 6-Apr-82 16:45 Sys 57 (128)
Subject: FROM: MIN

SUBJECT: INITIAL NOTIFICATION, CLASS II, FIRM INITIATED RECALL, RECALL COMPLETE.
TO: FDA, ALL REGIONS, DISTRICTS, SECTIONS AND RESIDENT POSTS
TWX ADDRESS: RUEVHGK RUEVFXO RUEVFXO RUEVFFX RUEVFOM
RUEVHFW RUEVFIL RUCHNFA RUEVHHQ RUEVHFE
RUCHNOZ RUEVFCF RUCHNOJ RUCHNOL RUWLSKX
RUWLSDP RUWLSPU RUWLSDH

FROM: FDA, MIN-DO, MARY-LOU DAVIS, R & E COORDINATOR, HFR-5495
INFO: LEN STAUFFER/HFK-113
REMLE GROVE/HFO-510
FED-State Relations/HFO-310
HFA-224
HFI-40
HFI-45
HFO-25
HFL-1
EUGENE STANLEY/HFR-53

APR 7
L 4/7/82
J 4-7-82
J 4.7.82
R

RECALL #: T-132-2 - Unipolar
T-133-2 - Bipolar

PAC: 78008

PRODUCT CODE: 74DX4

CF # OF RECALLING FIRM: 2124215

COUNTY: 123

JD/TA: 17

1. PRODUCT:

CPI MICROTHIN-DI, MODELS 0520 and 0620 - DEMAND PULSE GENERATOR: CPI MICROTHIN-PI, MODELS 0522 and 0622 - PROGRAMMABLE DEMAND PULSE GENERATOR; CPI MICROTHIN DII, MODELS 0521 and 0621 - DEMAND PULSE GENERATOR; and CPI MICROTHIN PII, MODELS 0523 and 0623 - PROGRAMMABLE DEMAND PULSE GENERATOR. MODELS 0520, 0521, 0522, and 0523 ARE UNIPOLAR AND MODELS 0620, 0621, 0622 and 0623 ARE BIPOLAR.

2. CODES:

MICROTHIN DI AND PI'S (520/522) SHIPPED PRIOR TO JANUARY 19, 1982 AND ALL MICROTHIN AND P2's (521/523) BUILT BEFORE JAN., 1981.

SERIAL NUMBER RANGE (NOT ALL S/N's INCLUSIVE):

MODEL #5201 - 144269/144307
MODEL #521 - 222496/225404
MODEL #522 - 143780/226349

MODEL #523 - 222531/225648
MODEL #620 - 140284/303317
MODEL #622 - 140337/142721
MODEL #623 - 222533/226097

3. RECALLING FIRM/MANUFACTURER:

CARDIAC PACEMAKERS, INC., 4100 N. HAMLINE AVE., PO BOX 43079, ST. PAUL, MN IS THE MANUFACTURER AND RECALLING FIRM AND THE MOST RESPONSIBLE FIRM.

4. REASON FOR RECALL RECOMMENDATION:

DURING DECEMBER, 1980 AND JAN. 1981, MICROTHIN PULSE GENERATORS, BOTH UNIPOLAR AND BIPOLAR MODELS, WERE DISTRIBUTED WITH SEAL SCREWS WHICH WERE TOO SHORT TO MAKE CONTACT WITH THE LEAD TERMINAL PIN AND TO ASSURE ELECTRICAL CAPTURE OF THE HEART. THESE SEAL SCREWS WERE BELOW THE MINIMUM SEAL SCREW STUD LENGTH OF 2.415 mm. CPI HAD RECEIVED 15 REPORTS (SIX UNIPOLAR, NINE BIPOLAR) OF SHORT SCREW PROBLEMS. THIRTEEN OF THESE INCIDENCES WERE DETECTED AT THE TIME OF IMPLANTATION. THE FIRM DID ADDITIONAL TESTING OF THE UNITS AND COULD NOT REPRODUCE INTERMITTENT OR PARTIAL CAPTURES. THERE WERE THREE VARIABLES WHICH COULD HAVE AN EFFECT ON THE ABILITY TO CAPTURE: (1) DIAMETER OF THE TERMINAL PIN (2) LENGTH OF SCREW AND (3) POSITION OF THE CONNECTOR BLOCK.

THE FIRM HAD FIXED THOSE UNITS STILL IN HOUSE AND INSTRUCTED THEIR SALES FORCE IN A MEMO DATED 1/21/81 TO CONTACT PHYSICIANS WITH DEVICES ON THE SHELF AND TO EXPLAIN THE PROBLEM AND IMPLANT TECHNIQUES. THE PROBLEM CAN BE DETECTED AT THE TIME OF IMPLANTATION. ALL STOCK STILL IN THE SALES FORCE's CONTROL WAS TO BE RETURNED (409 UNITS). THE FIRM DID NOT FEEL THIS WAS A RECALL ACTION AT THIS TIME BECAUSE THEY HAD NOT TAKEN ACTION ON ANY PRODUCT OUTSIDE OF THEIR CONTROL. THE BMD MET WITH THE FIRM ON 12/17/81 AS A FOLLOW-UP TO A LETTER SENT TO THE FIRM ON 12/1/81 GIVING THEM THE RESULTS OF BMD'S HEALTH HAZARD EVALUATION. MIN-DO ORIGINALLY LEARNED OF THE PROBLEM FROM A WRITTEN INQUIRY FROM A LAW FIRM IN GALVESTON, TX, DATED 10/7/81. AS A RESULT OF THE MEETING WITH BMD AND SUBSEQUENT INSPECTIONS BY MIN-DO ON 1/7, 14-82 and 2/8/82, MORE INFORMATION WAS GATHERED FROM THE FIRM ABOUT THE PROBLEM. THE FIRM MADE FURTHER EFFORTS TO LOCATE 35 UNITS WHICH PREVIOUSLY COULD NOT BE LOCATED. THEY HAVE NOW PROVIDED 98% ACCOUNTABILITY OF ALL UNITS INVOLVED. THEIR ACTION WAS CLASSIFIED AS A COMPLETED RECALL.

5. VOLUME OF PRODUCT IN COMMERCE:

THERE ARE NINE UNITS IN DOMESTIC DISTRIBUTION WHICH CANNOT BE LOCATED. ELEVEN UNITS WERE SHIPPED TO MEXICO THROUGH THE FIRM'S MEXICAN REPRESENTATIVE AND THE FIRM HAS BEEN UNABLE TO TRACE THESE UNITS BUT PRESUMES THEY HAVE BEEN IMPLANTED. FOUR UNITS WERE SHIPPED TO WEST GERMANY (MEDICAL KLINIK-VILLINGEN AND KRANKEHAUS BUSTEHUDE), THREE UNITS WERE SHIPPED TO ITALY, THREE UNITS WERE SHIPPED TO HOLLAND AND ONE UNIT WAS SHIPPED TO SPAIN. THE FIRM WAS UNABLE TO TRACE THESE UNITS ANY FURTHER AND PRESUMES MOST OF THEM HAVE BEEN IMPLANTED.

6. DISTRIBUTION PATTERN:

NATIONWIDE AND TO MEXICO, WEST GERMANY, ITALY, HOLLAND, AND SPAIN.

7. FIRM'S RECALL ACTION:

FIRM SENT OUT MEMO TO SALESFORCE ON 1/21/81. AFTER MEETING WITH BMD ON 12/17/81 FIRM CHECKED THROUGH THEIR INFORMATION TO TRY TO TRACE WHEREABOUTS OF 35 UNACCOUNTED FOR UNITS. FIRM WAS ABLE TO LOCATE FOUR DOMESTIC UNITS AND WAS UNABLE TO LOCATE NINE DOMESTIC UNITS. 22 FOREIGN DISTRIBUTED UNITS WERE ALSO NOT TRACEABLE. THE BUREAU AND THE FIRM FEEL THIS COMPLETES THEIR RECALL ACTION.

8. FIRM OFFICIAL:

KEVIN O'MALLEY, CORPORATE ATTORNEY
CARDIAC PACEMAKERS, INC.
4100 N. HAMLINE AVE.
ST. PAUL, MN 55164
612/631-3000

9. DISTRICT AUDIT PROGRAM:

THE RECALL ACTION IS COMPLETED. MIN-DO'S INSPECTION AND REVIEW OF THE FIRM'S RECORDS ON 2/8/82 PROVIDED FOR 98% ACCOUNTABILITY OF ALL UNITS INVOLVED. THIS WAS CONSIDERED A LEVEL A AUDIT REVIEW OF THE FIRM'S RECORDS. NO FURTHER AUDIT CHECKS WILL ISSUE.

APPENDIX K

October 26, 1981

Mr. Jack C. Brock
Mills, Shirley, McMicken & Eckel
700 First Hutchings - Sealy National Bank Building
Galveston, Texas 77550

Re: No. 81-39582 - Cardiac Pacemakers, Inc. vs. Ken W. Carnes

Dear Mr. Brock:

This is in response to your letters of October 7 and 14 addressed to Mr. Glen Rahmoller, concerning Cardiac Pacemakers, Inc.'s (CPI) Microthin-P1 pacing unit, models 620 through 623.

The Food and Drug Administration was neither aware, nor informed by CPI, of the problem with the set screw or of the action taken by the firm. This matter is being investigated to determine if the problem meets the criteria of a recall, as stated in the Federal Register of June 16, 1978 (43 FR 26202), copy enclosed.

Although FDA recommends that firms inform it of any problems, complaints or recalls a firm may have, there are no mandatory requirements for firms to do so. Such an action is presently voluntary. In many cases, we learn of such things from interested persons like yourself.

We hope this information has been helpful, and thank you for your interest in this matter.

Sincerely yours,

John H. Samalik
Recall and Notification Branch
Bureau of Medical Devices

Enclosure

JSamalik:10-22-81; R/D:rgc:10-23-81: Revised:HEButts:10-23-81; F/C:rgc:10-26-81

cc: HFK-113 (Pending)
HFA-224
HFK-450 (Rahmoller)
HFR-5495

APPENDIX L

TAB E

ATTACHMENT 1

INTERMEDICS INC.

MEMORANDUM

Date: October 23, 1981

To: Field Representatives

From: Kelley Atkinson, Director of Marketing

Subject: New Longevity Information on the Model 259-01 CyberLith IV

Enclosed are ten copies each of two new Technical Memos. The first memo concerns the CRC 802C/23 battery; the second concerns the 904/23 battery, also from CRC. These memos discuss the technical characteristics of the batteries and their estimated service lives (longevity) when used in the CyberLith IV. You will want to read them carefully to be sure you can easily recall the information in them.

These two memos are the result of a sophisticated and thorough technical evaluation of the 802 and the 904. Having advised you that this project was underway, we have been receiving inquiries from the field. The following is a compendium of some of those questions and the answers to them.

QUESTIONS AND ANSWERS ON 802C/23 AND
904/23 BATTERIES IN THE CYBERLITH IV

1. *Who are the memos being mailed to?*

   The mailing today is being sent to Intermedics field representatives only.

   We have another mailing going to the 259-01 clinical investigators in one week. That one will contain a general update on the CyberLith IV, the latest reliability data, and these two technical memos.

2. *What product changes associated with the new technical information will the clinician want to know?*

   There are only two: the estimated longevity and the elective replacement indicator for units containing 802C/23 batteries have been changed. There are no "quirks", tricky characteristics, or unexpected operating phenomena associated with the new data. Normal follow-up is all that is necessary. There are no other significant changes. Period.

   Learn the facts in the table (it's the same table in both memos) and you've got 90%+ of the information you'll need.

3. *What about the warranty? Does it change?*

Now, you weren't paying attention in #2 above or you wouldn't have asked that! Again, the only changes are the elective replacement indicator and the estimated longevity for 259-01s containing the 802C/23 (pacemaker serial numbers under 25,000).

There are no other changes. That includes the limited warranty.

4. *Is there any hurry in discussing these new facts with my implanters?*

Well, there are two things to keep in mind here:

1. The elective replacement indicator for 259s under serial number 25,000 increases from a nominal 7 ± 3 ppm to 12 ± 3 ppm. Your clinicians need to know this to avoid early explant.

2. You can assume that competition will get all this information and, having demonstrated an ethics vacuum on similar subjects in the past (readers of this memo at competitive headquarters take note), that they will seek to discredit you and the product through innuendo and the usual distortions.

   If you have properly informed your clinicians before the competitive salesman arrives, he gets egg on his face. If not, you may have more explaining to do.

5. *What else should I know?*

Be sure to note the data on the 904/23 -- it is an impressive battery. Longevity should be approximately nine years (100% pacing, DVI mode, nominal parameters).

Note also that wasteful programming, which is never desirable, should especially be avoided with the 802C/23 battery. Keep the pulse width down to a prudent level to avoid needless current drain while assuring capture.

6. *What if I have more questions?*

Call one of the following people:

Doug Gerrard
Kelley Atkinson
Dick Martin
Bob Senelly

7. *Where can I get more copies of the tech memos?*

Call Doris Riggan-Hudzietz at extension 1228.

AKA:blm
Encl.

TAB D ATTACHMENT 2

PRODUCT DESIGN

technical memo D5

Revised Longevity Estimates for CRC 802C/23 Batteries in Model 259-01 A-V Sequential Pacemakers

Introduction

This technical memorandum summarizes the test results of the 802C/23 battery under loads simulating the model 259-01 A-V sequential pacemaker. Analysis of long-term test data on 802C/23 energy cells from Catalyst Research Corporation has shown that the average service performance of these cells under pacemaker loads will be significantly less than originally projected for the model 259-01 pacemaker. The lowered performance expectation is a result of a greater and more variable rate of electrolyte resistance growth than that indicated by 802C/23 prototypes discharged under accelerated conditions. The shortened service life projections resulting from this analysis do not affect pacemaker operation except for a modification of elective replacement criteria.

Electrochemical Mechanism

The 802C/23-type of cell incorporates a soft depolarizer material that promotes the growth of large crystalline structures within the electrolyte. This is unlike the 900-series cells now used to power the 259-01 that have solid pelletized depolarizers. The larger and more variable size of the crystallites in 802-type batteries minimizes the grain boundaries along which lithium ions are free to migrate. This promotes faster electrolytic resistance growth at pacemaker loads than previously observed in accelerated discharge tests.

Analysis of the Data

Evaluation of 802C/23 cell performance in Intermedics pacemakers proceeded as follows:

The relationship between internal battery resistance and capacity expended was mathematically characterized as a function of external resistive load. Then the interaction between Intermedics 259-01 pulse generator circuitry and CRC batteries at successive states of discharge was simulated over the entire lifetime of typical 802C/23 cells. This process was repeated at the 5th, 50th, and 95th percentiles of the cell performance distribution. A typical series of such cell voltage curves for the model 259-01, pacing continuously in DVI mode into 500 ohms, is shown in Figure 1. These curves show that the performance of the 802C/23 battery falls significantly below that previously anticipated.

Effect on the Elective Replacement Criterion

Ordinarily, the elective replacement indicator of an Intermedics pacemaker design is selected near the beginning of the "knee" of the voltage/time curve to optimize longevity. For Intermedics pacemakers, this minimum battery voltage point is typically fixed at 2.2 volts in magnetic mode, corresponding to about 2.36 volts in automatic (non-magnetic) pacing mode. With the new 802C/23 voltage/time projections, this 2.2 volt point now occurs much earlier in the life of the battery. This yields extraordinarily high safety margins, or periods of safe pacing, following the occurrence of the previously selected elective replacement indicator. Consequently, Intermedics recommends shifting the elective replacement indicator point for the 259-01 with 802C/23 batteries to 2.0 volts in magnet mode. At that time the automatic (non-magnetic) mode battery voltage will still be 2.2 volts, ensuring more than adequate margin for safe pacing.

Accordingly, magnetic rate drop demarking elective replacement is changed from a nominal 7 ± 3 ppm to a nominal 12 ± 3 ppm. To determine the rate decrease recommended for a specific pulse generator, refer to the original pacemaker test data sheet and multiply the recorded rate drop by 1.7.

It should be emphasized that the magnet rate will decrease in proportion to the gradual decrease in battery voltage as it was designed to do, and this decrease is easily monitored by routine pacemaker follow-up. Other operating characteristics of the pacemaker are unaffected.

Conclusion

Intermedics' intensive analysis of all CRC life test data on 802C/23 cells points to the need for revised longevity expectations and adjusted elective replacement criteria for model 259-01 pacemakers containing this cell. This is due to the inherent tendency of soft depolarizer cells to develop electrolytic resistance under pacemaker loads at significantly higher rates than indicated by early prototype data.

Intermedics no longer manufactures pacemakers incorporating 800-series cells, including the 802C/23, having replaced them with Catalyst Research 904/23 cells. Equally intensive analysis has been done on the 904/23 cell, and longevity projections for the 259-01 are presented below for both cells. A detailed technical summary of the 904/23 analysis is contained in Technical Memo D6.

These projections for the median service life are conservative. However, the service life of an individual pacemaker can differ considerably from the median depending upon resistive load, programmed settings, and other variables.

Pacemaker operation is not compromised in any way by the new information. In fact, the period of safe pacing following the revised elective replacement indication is greatly increased in pulse generators containing 802C/23 type batteries because the replacement point occurs several years prior to the "knee" of the curve. The point at which prophylactic removal is indicated will simply appear sooner than originally projected. Normal pacemaker follow-up should be employed to monitor the performance of units containing 802C/23 type cells.

As with all programmable pacemakers, the service life of the 259-01 pacemaker can be increased by programming the pulse width of the unit to a value no higher than necessary to assure capture with adequate safety margin, thus conserving battery energy.

Douglas Gerrard, Ph.D.
Vice President Product Assurance

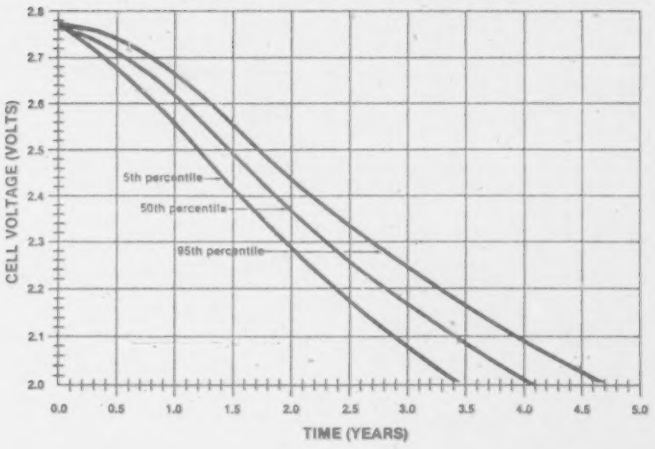
Table 1

Median Service Life Estimates, Model 259-01[1]

Cell	802C/23		804/23	
Pacing Modality	DVI	VVI	DVI	VVI
Elective Replacement Cell Voltage (Magnet Mode)	2.0 V	2.0 V	2.2 V	2.2 V
Elective Replacement Indication (rate slowdown)	12 ± 3 ppm	12 ± 3 ppm	7 ± 3 ppm	7 ± 3 ppm
Estimated Time to Elective Replacement Indication	2.9 yrs.	5.1 yrs.	9.2 yrs.	16.8 yrs.
Nominal Safety Margin[2]	1.2 yrs.	3.3 yrs.	2.5 yrs.	3.3 yrs.
Estimated Time to End of Service	4.1 yrs.	8.4 yrs.	11.7 yrs.	20.1 yrs.
Pacemaker Effectivity	259-01 serial numbers below 25,000		259-01 serial numbers above 25,000	

Figure 1

Cell Voltage Vs. Time[1] (Non-Magnetic Mode)
Model 259-01 Pacemakers with the CRC 802C/23 Battery



Intermedics Inc.

[1]100% pacing, 500 Ω load, nominal parameter settings, DVI mode.
[2]Safety margin is defined as the time between the elective replacement indication in magnet mode and the point at which the operating (non-magnetic) cell voltage reaches 2.0 volts.

©Intermedics, Inc., October 1981

technical memo D6

Longevity Estimates for CRC 904/23 Batteries in Model 259-01 A-V Sequential Pacemakers

Introduction

Utilizing a solid, pelletized depolarizer material, Catalyst Research Corporation has developed a new series of lithium iodine battery cells yielding consistently higher performance than their soft depolarizer predecessors. Intermedics' analysis of long-term test data on these 900-series cells shows a significant reduction in the growth rate of cell resistance with remarkably consistent performance from cell to cell. In fact, the accumulated performance data indicates that the relationship between internal cell resistance and capacity expended is virtually independent of external resistive load. This characteristic is ideal for applications in programmable cardiac pacing, where the load can vary over a wide range.

Electrochemical Mechanism

The solid pelletized cathode in 900-series cells exerts mechanical stress on the electrolyte during its formation, thereby inducing extensive electrolyte fracturing and numerous grain boundaries. This is in contrast to soft depolarizer cells such as the CRC 800 and 702E series that do not exert these stresses and thus have fewer grain boundaries. (See Technical Memo D5). Since the 900-series pellet remains solid throughout cell life, this fracturing process continues as the cell is discharged, resulting in greater freedom of ion movement and thereby higher cell voltage throughout useful life. This fracturing process overwhelms other factors which can influence crystal size so that the internal resistance of 900 series cells is low, reproducible, and substantially independent of changes in cell current.

Analysis of the Data

Voltage-versus-time measurements were made with 904/23 cells under various loads ranging from 5KΩ to 200KΩ. Analysis of this data revealed a relationship between electrolyte resistance growth and capacity expended that is independent of external resistive load. In one special test series, the operating load was switched at 0.5 amp hour capacity expended from 5KΩ to 10KΩ. The load was changed again at 1.2 amp hours capacity expended from 10KΩ to 20KΩ. Throughout this test there were no detectable changes in the growth rate of resistance versus capacity expended (see Figure 1).

This property of the 904/23 cell, together with its high degree of performance consistency, enables precise projections of longevity to be made under various pacemaker operating conditions. Longevity projections are generated by simulating the behavior of the system through twelve hour increments of operation. That is, cell voltage, and pacemaker parameters that are affected by cell voltage, were recomputed at each of these twelve hour increments throughout the simulated life of the system. The consequent cell voltage-time curve for the 259-01 pacemaker under nominal conditions is shown in Figure 2.

Conclusions

Intermedics' analysis of CRC 904/23 power cells indicates that their solid pelletized construction yields significantly better performance than that observed in earlier 800-series cells employing a soft depolarizer material. This is reflected in much greater service life expectations, a high level of consistency from one battery to another, and battery capacity that is independent of load.

Median life expectancies of 259-01 pacemakers containing 904/23 and 802C/23 batteries are compared in Table 1 for both DVI and VVI modalities. Also note in the table that safety margins following the elective replacement indication are more than adequate with either power source.

Douglas Gerrard, Ph.D.
Vice President Product Assurance

Table 1

Median Service Life Estimates, Model 259-01[1]

Cell	802C/23		904/23	
Pacing Modality	DVI	VVI	DVI	VVI
Elective Replacement Cell Voltage (Magnet Mode)	2.0 V	2.0 V	2.2 V	2.2 V
Elective Replacement Indication (rate slowdown)	12 ± 3 ppm	12 ± 3 ppm	7 ± 3 ppm	7 ± 3 ppm
Estimated Time to Elective Replacement Indications	2.9 yrs.	5.1 yrs.	9.2 yrs.	16.8 yrs.
Nominal Safety Margin[2]	1.2 yrs.	3.3 yrs.	2.5 yrs.	3.3 yrs.
Estimated Time to End of Service	4.1 yrs.	8.4 yrs.	11.7 yrs.	20.1 yrs.
Pacemaker Effectivity	259-01 serial numbers below 25,000		259-01 serial numbers above 25,000	

[1]100% pacing, 500Ω load, nominal parameter settings.

[2]Safety margin is defined as the time between the elective replacement indication in magnet mode and the point at which the operating (non-magnetic) cell voltage reaches 2.0 volts.

The figures shown in the table tend to be conservative because of the 100% pacing assumption. Significant increases in longevity can be obtained by adjusting the pulse width to a value no higher than needed to maintain capture with adequate safety margin. For example, a pulse width change from .61 msec to .47 msec can add 20 percent or more to the expected life of the pacemaker.

Figure 1

Battery Resistance Vs. Capacity Expended
904/23 Battery Load 5K - 10K - 20K

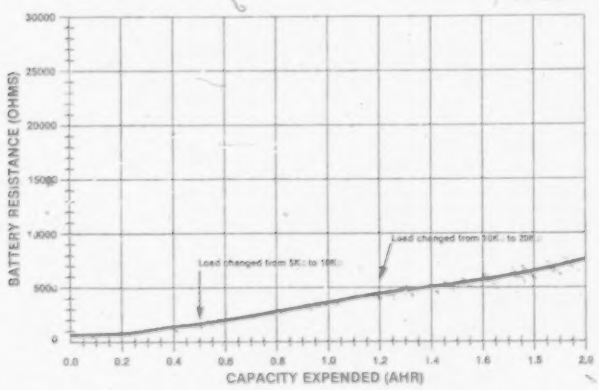
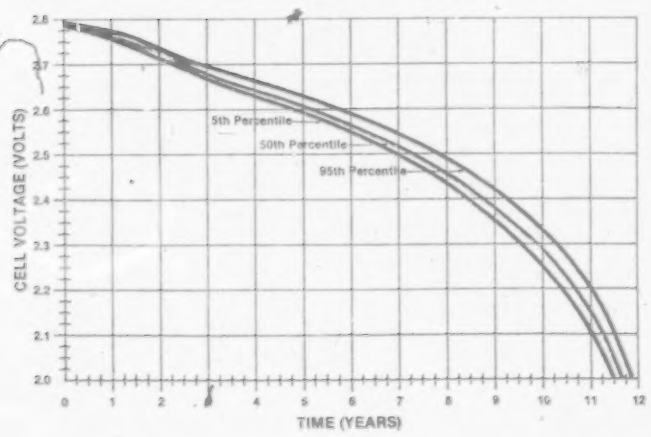


Figure 2

Cell Voltage Vs. Time[1] (Non-Magnetic Mode)
Model 259-01 Pacemakers with the CRC 904/23 Battery



[1]100% pacing, 500 Ω load, nominal parameter settings, DVI mode

Intermedics, Inc., October 1981

Intermedics Inc.
1T03-CA-110

APPENDIX M

Associate Director for Compliance, HFK-100
Bureau of Medical Devices

Approval of Class I Recall
CyberLith IV Model 259-01 A-V Sequential Pulse Generator - ACTION

Joseph P. Hile, Associate Commissioner
for Regulatory Affairs, HFC-1
Through: Acting Director,
Bureau of Medical Devices, HFK-1

Firm: Intermedics, Inc.
Freeport, TX
AF 44-187

ISSUE

Whether the action initiated by Intermedics, Inc. on the CyberLith IV Model 259-01 A-V Sequential Pulse Generator With CRC 802C/23 Batteries should be classified as a Class I recall.

BACKGROUND

The CyberLith IV Model 259-01 is a hermetically sealed, multi-programmable unipolar cardiac pulse generator. The device may be programmed for operation in any of three modes; demand ventricular inhibited (VVI), atrioventricular sequential fixed rate, and atrioventricular sequential demand (AVT).

The implantable generator is used for long term treatment of impulse formation or conduction disorders which result in slow or fast heart rates and heart stoppages unresponsive to drug therapy.

The battery manufacturer, CRC, informed Intermedics, Inc. in January 1981 that the 800 series batteries were not meeting the longevity projections initially furnished to Intermedics in 1979. Following an analysis of CRC data and a subsequent meeting with CRC personnel, Intermedics agreed that analysis of the data indicated the need for new longevity projections.

As a result, Intermedics issued two technical memoranda in October 1981 (TAB D) and a memorandum to field representatives, dated October 23, 1981 (TAB E).

BMD was first informed of this problem through a consumer complaint on 12-23-81 and trade complaint on 12-28-81. Immediate contact with the firm resulted in a PMA supplement received on 1-26-82. In the interim, BMD requested an establishment inspection (1-21-82) which was received from Houston Station on 2-22-82.

Technical Memo D5 informs users of the revised longevity estimates for the CRC 802C/23 batteries in the subject pulse generator. It states that average service performance level of the cells under pacemaker loads will be significantly less than originally projected. The firm's conclusion is that there

is a "need for revised longevity expectations and adjusted elective replacement criteria for Model 259-01 pacemakers containing this cell." Median service life estimates were reduced from 16 years to 5.1 years in the VVI mode and from 10 years to 2.9 years in the DVI mode. The Technical Memo D5 concludes that the newer CRC 904/23 batteries yield better performance than the earlier 800 series. The firm is currently manufacturing Model 249-01 with the CRC 904/23 batteries.

Intermedics shipped 4,816 Model 259-01 pacemakers with 800 series batteries and has received 4,090 "patient registration and implant data" forms. The firm estimates that 3,698 Model 259-01 pacemakers with 800 series batteries are still implanted. Intermedics began distribution of the Model 259-01 pacemaker to the clinical investigators in late 1979.

HEALTH HAZARD EVALUATION

The Bureau of Medical Devices' Health Hazard Evaluation Committee has concluded that the failure of physicians to have available directions, longevity data and elective replacement criteria, may adversely affect patient management. This situation is serious or life-threatening, and is likely to occur in patients when the pacer has been implanted for over 3 years, if the patient's physician has not received this information (TAB B).

RECOMMENDATION

We recommend that Intermedics' Technical Memoranda D5 and D6, concerning the CyberLith IV Model 259-01 Pulse Generator which informs physicians of a significant revised longevity estimate, be classified as a Class I recall.

A proposed text of a teletype to the firm is attached (TAB A).

Ann B. Holt, DVM

Attachments
TAB A - Proposed Teletype
TAB B - Health Hazard Evaluation
TAB C - Recall Strategy
TAB D - Technical Memoranda D5 and D6
TAB E - Intermedics' Memorandum Dated October 23, 1981
TAB F - Recommendation for Recall TWX

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by: James S. Merritt, HFK-113, 2-25-82, 427-8110

JSMerritt:2-25-82; Initial:LJStauffer: 3-1-82; R/D:rgc:3-1-82; Revised:HEButts:3-
Revised:JSMerritt:3-3-82; Initial:LJStauffer:3-3-82; Redrafted:rgc:3-4-82
Initialed:LJStauffer:3-8-82; HEButts:3-8-82; ABHolt:3-8-82; F/C:rgc:3-8-82

cc: HFC-1 HFC-22 HFY-1 HFK-113/2 HFI-40 HFO-510 HFA-224 HFK-110 HFK-1
TELETYPE ONLY: HFK-110 (Board) HFK-114 (Pink) HFK-100/2
Field Reg. Director and Monitoring Reg. Director
(HFR-61) (HFR-6100)

APPENDIX N

FOOD AND DRUG ADMINISTRATION'S PACEMAKER REGISTRY - COST

June 1, 1974 to May 31, 1975	$100,706
1975 1976	131,843
1976 1977	133,400
1977 1978	137,496
June 1, 1978 to Sept. 30, 1978	36,664
Oct. 1, 1978 to Sept. 30, 1979	165,525
1979 1980	179,500
1980 1981	100,000

APPENDIX O

July 14, 1982

PACEMAKER MANUFACTURERS

Current manufacturers who marketed pacemakers prior to May 28, 1976.

Medtronic
Cardiac Pacemakers, Inc. (CPI)
Intermedics
Pacesetter Systems
Cordis
Siemens-Elema
Telectronics
Biotronik
Coratomic
American Pacemaker

Manufacturers who dropped out of the U.S. market since 1976.

General Electric	1976
Edwards	1978
Vitatron	1979
Arco	1980
American Technology	1980
Medcor	1981
Synthemed	1982

Manufacturers who entered the U.S. market since 1976.

ELA	1979
Cook	1981
Synthemed	1981

This list was prepared from information provided by pacemaker manufacturers.

APPENDIX P

Intermedics Inc.

August 28, 1981

REGISTERED MAIL

Dear Dr.

SUBJECT: ARCO PULSE GENERATORS (Li-3, ARCOlith 3 and ARCOlith 4)
ELECTIVE REPLACEMENT RECOMMENDATIONS

The purpose of this letter is to provide information to you on pulse generators which, according to data provided to us by the pacemaker operations of ARCO Medical Products Company, Leechburg, PA, a subsidiary of Atlantic Richfield Company, have been implanted in your patients.

As you are aware, on October 9, 1980, Intermedics acquired some of the assets and assumed the written warranties for pulse generators manufactured by the pacemaker operations of ARCO Medical Products Company. Prior to the acquisition of ARCO by Intermedics, ARCO issued advisories on three pulse generator models manufactured by ARCO in Leechburg, Pennsylvania, from 1975 to 1978; namely, Models Li-3, ARCOlith 3 and ARCOlith 4, all possessing lithium thionyl chloride batteries. ARCO stated that longevity and end-of-life indicator claims previously designated should be modified. In addition, ARCO recommended a telephone monitoring protocol to detect premature battery depletions as well as an elective replacement recommendation if telephone monitoring was deemed too rigorous for satisfactory patient follow-up.

Intermedics, recognizing its responsibility for patient safety and the ARCO written warranty obligations, has been evaluating performance data on ARCO models since the acquisition of ARCO by Intermedics. ARCO pacemakers were evaluated by monitoring and analyzing field performance data, evaluating returned units, as well as reviewing all technical data provided to Intermedics by ARCO. The above-referenced technical analysis has required several months and now suggests that three models, specifically, Li-3, ARCOlith 3 and ARCOlith 4 have been exhibiting premature battery depletion without adequate end-of-life indications.

P.O. Box 617, Freeport, Texas 77541 • Phone: (713) 233-8611 • Telex: 792503

Because it is Intermedics' policy to consider patient safety as our first priority, we are alerting you to the updated status of the aforementioned ARCO pulse generator models.

ARCO Li-3, ARCOlith 3 and ARCOlith 4 pulse generator performance data have been carefully analyzed by Intermedics' technical staff, and their conclusions follow:

* data indicate that the chance of battery depletion greatly increases in the 39th month after implant.

* battery depletions have occasionally been manifested by an abrupt cessation of output that may occur between weekly monitoring schedules.

Intermedics recommends the following: ALL REFERENCED ARCO PULSE GENERATORS SHOULD BE PROPHYLACTICALLY REPLACED AT THE DISCRETION OF THE PHYSICIAN BY THE 34TH MONTH AFTER IMPLANT, IF EXPLANT IS NOT CONTRAINDICATED BY THE MEDICAL CONDITION OF THE PATIENT.

In the interest of facilitating this elective procedure, Intermedics will honor the patient reimbursement policies of ARCO Medical Products for those Li-3, ARCOlith 3 and ARCOlith 4 pulse generators replaced within the specific warranty period. Intermedics has also expanded the options available to you in replacing the specified models. The warranty and other options available to you and your patients are attached.

Whichever option you elect to choose, remember that the explanted ARCO unit must be returned to Intermedics, Inc.,--together with the removed pulse generator data form--within 30 days of explant to satisfy credit requirements. Your Intermedics representative is prepared to assist you in this matter, including a review of pulse generator models available for replacement.

From the best information available to us from ARCO, we have included two copies of a list of your patients we believe to have one of the subject ARCO pulse generators, together with pertinent implant data. In the event the status of some patients has changed and ARCO or Intermedics has not been notified, please note such changes on one of the implant data lists and return to Intermedics in the enclosed self-addressed envelope. Beyond that, we suggest you contact our Clinical Engineering staff with any other questions you may have in this matter. They can be reached via our Toll-Free number (1-800-231-2330, Ext. 1240) or by calling collect (713-233-8611, Ext. 1240).

Our action in this matter is strictly voluntary, and we have registered our recommended elective advisory procedure with the Food and Drug Administration (FDA).

Please assist us in confirming the receipt of this letter by signing the enclosed copy in the appropriate block and return to Intermedics in the self-addressed envelope provided. We appreciate your cooperation, and we stand ready to help in any way possible to minimize your concerns and those of your patients.

Sincerely,

INTERMEDICS, INC.

Douglas J. Gerrard

Douglas J. Gerrard, PhD
Vice President, Product Assurance

DG:lk

Enclosures

I ACKNOWLEDGE RECEIPT OF, AND HAVE READ, THE SUBJECT LETTER:

_____ _____
Signature Date

_____
Please print name

Leechburg, Pennsylvania 15656
Telephone 412 845 8111
TWX 510 467 8603

SENT TO FOLLOW-UP SERVICES

WITH A COPY OF DEAR DOCTOR LETTER

(Domestic)

May 16, 1980

Enclosed you will find a copy of the letter with attachments that we are sending to the physicians who have implanted ARCOlith 4 (LI-3) and ARCOlith 3 pulse generators or who are currently following patients with these units.

You may use this as guidance for the pacemaker implantees you are following for other physicians.

If you have any questions, please call or write to me.

Sincerely,

ARCO MEDICAL PRODUCTS COMPANY

Arthur C. White
Manager, Quality Assurance and Regulatory Affairs

Enclosure

APPENDIX Q

PRELIMINARY INVESTIGATION SUMMARY AND CLOSING FORM

(1) 10.2.A Preliminary Investigation Number: 781-0033

Organization Name (to Div. level): Competition Org. #: 1030 11

(2) Respondents(s): (check box at right if respondent was contacted)

a) Medtronics,Inc. and other pacemaker manufacturers and related suppliers ☐ None contacted as respondents.
b) including: Intermedics,Inc.;Cardiac Pacemakers,Inc.;Mennan Great Batch ☐
c) Electronics,Inc.;Teletronics;Cordis Corp.;American Hospital Supply ☐
d) ☐

(3) Reason for Closing: (circle the applicable code number):

Opening of Formal Investigation 1
No Violation 2
Minor Violation Corrected 3
Investigation Transferred 4
Other (specify) _____ 5

(4) Recommendations and Summary of Circumstances Surrounding Closing: (attach continuing pages as necessary)

Recommendation that all aspects of case be closed and that certain information be transferred to the Department of Justice because of finding that, under most theories,there was no violation and, under one theory, there may be a violation but this is better investigated by the DOJ. See attached memorandum.

Attorney/CPS: Patricia S. Bangert Date: December 11,1978

(5) Approvals:

Div./Regional Director — M 12 D 18 Y 78 date

Bureau Director/Assistant — M D Y date

Office of Regional Operations — date

BC Asst. Dir. Evaluation — date

COPIES white: Preliminary Invest. File yellow: Data Processing (Mgmt. Div.)
green: Preliminary Records Unit pink: Bureau Clearance

FTC 6-76 (10/74)

Pacemaker Industry (Medtronic, CH7-0033)
Staff Recommendation: Closing as to all aspects and forwarding certain information to the Department of Justice

SUMMARY

Since the first pacemaker was implanted in 1960, the domestic pacemaker market has grown to 96,000 units in 1977 (approximately $240,000,000). This is a growth of 60,000 units from just 1970. The market is dominated by four major firms: (1) Medtronic with a 46% share of the domestic pacemaker market in 1977; (2) Cordis with a 16.7% share; (3) CPI with a 12% share; and (4) Intermedics with a 10% share. In addition, there are approximately 15 smaller firms which together held a 16% share of the domestic pacemaker market in 1977. Medtronic, which had a virtual monopoly of the market in the sixties, has gradually lost market share due primarily to its late introduction of innovative features and large recalls in the last 3 years.

Price has never played an important part in consumer choice due to the life support function of pacemakers, and the fact that a third party usually pays for them. With reliability becoming less of a factor, and with product differentiation diminishing (no major breakthroughs are foreseen), reputation through service and quality of sales force has become increasingly important.

Structural Analysis

Staff recommends that no monopolization or attempt to monopolize case be brought against Medtronic since it does not have monopoly power and is steadily losing market share in what is now a highly competitive industry. Although 4 firms control over 80% of the market, a shared monopoly case is not recommended since no cooperation among the manufacturers is seen, and there is indication that price competition will become apparent as product differentiation diminishes. It is recommended that the four firms be watched for signs of cooperation.

Analysis of Practices in the Pacemaker Industry

(1) Manufacturers of pacemakers have been offering lifetime warranties and have been giving away monitoring devices (transmitters are given to patients, receivers are consigned to physicians) and/or follow-up monitoring services, potentially creating an imbalance in the service market through economic power in the pacemaker market.

Potential application of a tie-in theory was rejected because there is no coercion, no evidence that patients are losing choice in monitoring services, and no evidence of a substantial impact on competition to show a public interest. Moreover, consumers benefit from the free devices and services.

Staff recommends that there be further scrutiny of allegations that some warranties are communicated to physicians but not patients and that lifetime warranties do not cover full replacement costs. This could be done through the Dallas Regional Office which is looking into pacemaker warranties and other health and safety features of pacemakers.

(2) There are allegations that certain pacemaker manufacturers (primarily Intermedics) have given or are giving bribes to physicians to induce them to implant their own pacemakers. Alleged bribes consist of money, stock in the company, land, free trips and use of credit cards, and fees for work never performed. There is also some indication of ties between manufacturers and physician groups.

Since detailed information is unavailable without process and since staff presently has been unable to uncover evidence of substantial competitive impact, no further Commission action is recommended. Rather, staff recommends forwarding the appropriate information to the Department of Justice which staff believes is better equipped to investigate specific instances of bribery.

NEVER DONE WHY NOT?

Presented below are a number of comments, a discussion of which prior to closing may be beneficial.

(1) The memo does not discuss whether the consigment policy could create an additional barrier to entry into the pacemaker market. Additional technological and contractual data would be necessary to make the determination. If, for example, each of the major brand receivers can only be used to monitor their own brand pacemakers, and if a doctor's office can only accomodate four receivers, the doctor may be effectively precluded from purchasing any other brand.

(2) The consignment policy was not discussed in the bribery section of the memo; but in light of the allegations of overt bribes, the policy may not be fundamentally different than giving the doctor the cash with which he furnishes his office.

(3) The nature and size of the reported bribes (stock, land, etc...) suggests corporate approval rather than a case of unrelated acts of overly agressive salesmen. The competitive impact, or at least potential impact, of the reported bribes therefore may be underestimated.

(4) If the allegations of close links between manufacturers and physician groups are true, a situation with particularly high anticompetitive potential may exist as the effects of the consignment policy/bribery become amplified.

(5) If bribery is part of a corporate policy, the scheme can be attacked as a deceptive practice without a showing of injury to competition. Consumer deception is at the very heart of the problem. Doctors aren't being bribed to tell patients they are salesmen.

Although staff recommended closing the present investigation, it also recommended that the four large pacemaker manufacturers be watched for signs of cooperation. The parallel, if not cooperative, potentially barrier-raising activity in the area of related services should be one of the areas closely watched even if the investigation is closed. The competitive effects of the technical tie-in may be more significant in the pacemaker market than in the markets for the services themselves.

With regard to viewing the consignment policy as analogous to bribery, even if the present investigation is closed, the information compiled thus far with regard to the policy may be helpful to rulemaking proceedings on physician financial interest in pharmacies. A second look at this and related areas (of free samples and supplies) may be in order after the Commission has had an opportunity to formulate a policy in the ongoing rulemaking proceedings.

Comments 3 and 4 are meant only to indicate that the competitive effects stemming from the various allegations may be broader than initially foreseen, while comment 5 is meant to provide a basis for Commission action if the competitive effects are still found to be somewhat short of substantial.

OPTIONAL FORM NO. 10
JULY 1973 EDITION
GSA FPMR 101-11.6

UNITED STATES GOVERNMENT

Memorandum

TO : Alfred F. Dougherty, Jr., Director,
Bureau of Competition

DATE: December 8, 1978

FROM : Patricia S. Bangert, Attorney,
Bureau of Competition

SUBJECT: Recommendation that the informal investigation, Medtronic, CH7-0033, be closed and that certain information be forwarded to the Department of Justice.

I. Introduction

Staff*/ informally investigated the pacemaker industry after allegations of violations of the antitrust laws occurring therein had been made. The investigation included a study of the structural and behavioral aspects of that industry. Public records, industry studies and interviews with industry members (manufacturers, sales representatives, hospital administrators and physicians) comprise the "record" compiled in this matter.

The compiled data indicates that the investigation should be closed. At one time, it was felt that the only firm in the industry with more than a 15 percent share of the market -- Medtronic with a 45 percent share -- might be classified as a monopolist or at least as a firm attempting monopolization. The facts do not bear this out. The industry is in fact highly competitive and the dominant firm is steadily losing market share.

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*/ Steve Hom, Student Assistant (Legal), worked with me this summer in interviewing witnesses and otherwise gathering information in this matter. He also made himself available for discussions about the case and participated in such discussions once he returned to school.

Buy U.S. Savings Bonds Regularly on the Payroll Savings Plan

A highly competitive industry, though, can breed unfair or deceptive acts or practices. In this case, it was alleged that one manufacturer new to the industry -- Intermedics -- has used commercial bribery to gain market share.*/ The investigation failed to prove that this was the case. Instances of bribery probably did occur but staff was unable to gather any concrete evidence of this during its informal investigation. To gather such evidence would require many more resources and an expertise in criminal-type investigations. Since staff was unable to show a substantial competitive impact due to commercial bribery such that addition resources and expenditures are warranted, staff recommends that the matter be turned over to appropriate people in the Department of Justice who can investigate specific allegations of bribery and bring specific charges against the participants.

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*/ Intermedics went from a one percent market share in 1974 to a ten percent market share in 1977.

II. The Pacemaker Industry

A. History of the Pacemaker Industry

A pacemaker consists of a generator and a lead -- the generator sending electronic impulses through the lead into the heart. The electronic impulses stimulate the heart -- causing the proper heartbeat -- when the heart's natural electrical system fails to operate.

The first pacemakers to be implated in human beings were produced in the early 1960's. The early pacemakers, powered by mercury zinc batteries, generated a continuous electrical impulse, whether the heart's natural stimulation process was functioning or not -- thus the name "fixed rate pacemakers." Medtronic manufactured and sold the first implantable pacemakers -- having a virtual monopoly of the market for a short period of time.*/ Cordis, though, entered the market shortly thereafter, being followed at later dates by General Electric, Warner-Lambert (American Optical) and others.**/ Despite the competition,

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*/ A good history of the beginning of the pacemaker industry is contained in a Medtronic pamphlet Toward Man's Full Life, , 1975. A more detailed medical description of pacemakers is contained in Tyers and Brownlee, "Current Status of Pacemaker Power Sources," The Annals of Thorasic Surgery Vol. 25, No. 6 (June, 1978) pp. 571-587. See Staff Interview with Brown and Miller (Medtronic), Atlanta, Georgia (July 27, 1978) (hereinafter referred to as "Medtronic Interview"), for a history of the pacer industry.

**/ Staff Interview with Finch and Bernstein (Cordis), Miami, Fla. (July 20, 1978) (hereinafter referred to as "Cordis Interview").

Medtronic took a predominant share of the pacemaker market.

The first major technological development in the pacemaker industry was the "demand" pacemaker. This pacer generated electrical impulses to stimulate the heart only when the heart's natural pacing system disfunctioned. The demand pacemaker was in general use by the late 1960's.*/

The next major technological development was the lithium powered pacemaker. While pacers powered by mercury zinc batteries could be expected to function effectively for 2 to 3 years, the lithium powered pacers are expected to last from 6 to 10 years,**/ thus eliminating costly surgical replacement procedures. While Medtronic researchers had been working on a lithium powered pacer, the lithium pacemaker was introduced by Cardiac Pacemakers, Inc. (hereinafter referred to as "CPI") in 1973. CPI had been formed in 1972 by former Medtronic employees.***/ Also taking advantage

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*/ Staff Interview with Blaney, Cluthe, Stevens and Wheeler (Medcor), Hollywood, Fla. (July 19, 1978)(hereinafter simply referred to as "Medcor Interview").

**/ Staff Interview with Kennedy, Allen and Brooten (Pacemaker Diagnostic Clinic), Gainesville, Fla. (July 10, 1978)(hereinafter referred to as "PDC Interview"); Staff Interview with Beutel and Anderson (Intermedics), Freeport, Texas (August 22, 1978)(hereinafter referred to as "Intermedics Interview").

***/ Staff Interview with Cardiac Pacemakers, Inc., St. Paul, Minn. (August 3, 1978)(hereinafter referred to as "CPI Interview").

of the newly created market for lithium powered pacers was Intermedics, a company formed in 1973 by another former Medtronic employee.*/

The latest major technological advancement in the pacemaker industry is the "programmable" pacer. With the programmable pacer, the rate of the electrical impulses, as well as other pacer functions, can be programmed and reprogrammed from outside of the patient's body -- the surgeon no longer has to employ surgical procedures to change pacemaker functions. The first rate-programmable pacer was introduced by Cordis in the early 1970's.**/ At this point, all of the major manufacturers are working on or have a programmable pacer although Intermedics' Cyberlith, now in the clinical testing stage, is said to be the most advanced programmable unit.***/ Industry observers see programmability as the key to competition in the pacemaker industry in the future, no other major technological developments being in sight.****/

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*/ Intermedics Interview.

**/ Interview with Cordis. See also, F. Eberstadt & Co., Inc. "Pacemakers--Industry and Company Prospects" p. 5 (March 1, 1978) (hereinafter referred to as "Eberstadt Study"), for a discussion of programmability.

***/ Intermedics Interview; Eberstadt Study at p. 41.

****/ Eberstadt Study at p. 5; Morgan Stanley & Co., "1978-1975 Outlook for the Domestic Pacemaker Market" at pp. 17-19 (March 9, 1978)(hereinafter referred to as "Morgan Stanley Study"); Medtronic Interview; Cordis Interview.

These major technological developments and aggressive new competitors to exploit or explore them helped to cause a slippage in Metronic's once predominant position in the market by the middle seventies. At the present time, as will be discussed in more detail elsewhere, Medtronic holds the number one position in the market but CPI and Intermedics are fast gaining market share. Cordis remains among the top four firms but firms like General Electric and Warner-Lambert which also entered the pacemaker market in the 1960's have dropped out or presently hold relatively minor market shares.*/

B. Size of the Pacemaker Market

Since the first pacemaker was implanted in 1960, the domestic pacemaker market has grown to 96,000 units in 1977. This is a growth of 60,000 units from just 1970.**/ Although a few industry observers consider the pacer market to be mature, most projections indicate that the market will continue to grow due to: (1) the appearance of new indications for pacemakers; (2) intensification of educational focus on pacemaker utilization; (3) advancement in diagnostic standards and techniques; and (4) steady expansion of the number of patients experiencing serious enough heart difficulties to require the use of pacemakers.***/

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*/ See discussion of market structure, below.

**/ Morgan Stanley Study at pp. 6 and 14.

***/ Ibid at pp. 7-8.

In 1977, 83% of pacemakers sold (80,000 units) were lithium powered demand pacemakers with the remaining 17% being non-lithium, usually mercury zinc battery powered pacers.*/ Programmable units represent 15% of the pacemaker market at the present time.**/

C. Structure of the Pacemaker Market

The pacemaker market is dominated by four major firms: (1) Medtronic with a 46% share of the domestic pacemaker market in 1977; (2) Cordis with a 16.7% share; (3) CPI with a 12% share; and (4) Intermedics with a 10% share. In addition, there are approximately 15 smaller firms which together held a 16% share of the domestic pacemaker market in 1977.***/

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*/ Graf and Grein (Eli Lilly), "A Business Analysis of Cardiac Pacemaker, Inc. - Lilly Diversification Program" (July 6, 1978) (hereinafter referred to as "Lilly Study").

**/ Morgan Stanley Study at pp. 13 and 17.

***/ Morgan Stanley Study at p. 6. These research estimates are confirmed generally by interviews with industry members.

98-116 O—82——12

The chart below sets out and expands market share and unit sales statistics:

Estimated Domestic Pacemaker Market Shares*
(Units in Thousands)

	1974	1975	1976	1977	1978	1979
U.S. Market						
New Implant	38,000	46,000	61,000	70,000	79,000	89,000
Replacement	31,000	36,000	30,000	26,000	26,000	33,000
Total	69,000	82,000	91,000	96,000	105,000	122,000
Company Share						
Medtronic	44,000	50,000	48,000	44,000**	44,000**	50,000
Percent	63.8%	60.9%	52.7%	45.8%	41.9%	41.0%
Cordis	14,000	13,000	14,000	16,000	20,000	24,000
Percent	20.2%	15.8%	15.4%	16.7%	19.0%	19.7%
CPI	2,000	4,000	9,000	11,000	13,000	15,000
Percent	2.9%	4.9%	9.9%	11.5%	12.4%	12.3%
Intermedics	1,000	3,000	6,000	10,000	15,000	19,000
Percent	1.4%	3.7%	6.6%	10.4%	14.3%	15.6%
All Other	8,000	12,000	14,000	15,000	13,000	14,000
Percent	11.6%	14.6%	15.4%	15.6%	12.4%	11.5%

The chart shows several important factors of the structure of the domestic pacemaker market. First, Medtronic, which had a virtual monopoly of the market in the sixties, has gradually but perceptibly lost substantial market share and will probably continue to do so. Second, Cordis, the perennial second in the industry has also lost market share but will probably stabilize its share in the future. Finally, CPI and Intermedics, the fresh new kids on the block, have gained a relatively large share of the market presumably at the expense of Medtronic and Cordis.

---

*/ Morgan Stanley Study at p. 6.

**/ Excludes the impact of "recall" unit sales.

According to industry sources, the decline in Medtronic's market share is attributable to several factors. Most important of these are Medtronic's large recalls and late introduction of lithium pacemakers.*/ Medtronic recalled 30,000 units in the last 3 years which probably caused some physicians to switch to other brands of pacers.**/ In addition, Medtronic was late -- after CPI and Intermedics -- in introducting a lithium powered pacer. At least one physician told this interviewer that one reason he does not use Medtronic at the present time is because the company "held back" the lithium powered pacer.***/

Implicit in the above mentioned factors of course is the existence of other firms offering stiff competition to the market leader. CPI had an initial edge on its competitors with the lithium powered pacemaker although competitors were quick to produce their own version of the longer lasting pacer. And in an industry where product reliability is one of the key competitive factors, CPI could

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*/ Staff Interview with Worzewski (Biotronics), St. Petersburg, Fla. (July 18, 1978) (hereinafter referred to as "Biotronics Interview"); Intermedics Interview; Medcor Interview; Medtronic Interview; Morgan Stanley Study at p. 3.

**/ Lilly Study.

***/ Staff Interview with Dr. Littleford, Orlando, Fla. (August 2, 1978) (hereinafter referred to as "Littleford Interview"); Staff Interview with Dr. Burton, Orlando, Fla. (August 23, 1978) (hereinafter referred to as "Burton Interview").

boast -- up to the recall this year -- that it had had not a single recall.*/ A fact which should be noted here is that Eli Lilly has announced its intention to acquire CPI. The Bureau is looking into this proposed merger.

Intermedics has a reputation for innovative products and an aggressive sales force -- both of which may be mixed blessings. Intermedics was one of the first pacer firms to produce a lithium powered pacer and is currently producing a very thin pacer and a unit in clinical testing, the Cyberlith, which promises to be the most advanced programmable pacer on the market.**/ There are allegations, though, that the Intermedics units are marketed too quickly and lack a certain reliability.***/ Also, Intermedics has one of the largest and most aggressive sales forces in the industry -- many of its salespersons coming from Cordis and Medtronic.****/

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*/ A study done for Eli Lilly in anticipation of its acquisition of CPI showed that for the physician the number one factor in choosing a pacemaker is reliability, Lilly Study. See also, CPI Interview. See, Eberstadt Study, at pp. 23-27 and Morgan Stanley Study at p. 4 for an overview of CPI.

**/ Eberstadt Study at pp. 37-41; Morgan Stanley Study at p. 4; Burton Interview.

***/ Burton Interview; Staff Interview with Dr. Tew, Orlando, Fla. (August 23, 1978); Littleford Interview.

****/ Eberstadt Study at p. 37; Morgan Stanley Study at p. 5. There has been litigation between Medtronic and Intermedics over these employee switches on the basis of non-competition clauses in Medtronic salesperson's contracts. See Medtronic Interview.

Some physicians complain, though, that the Intermedics' sales personnel are "too pushy" and there are allegations of unorthodox or illegal sales tactics.*/ At any rate, Intermedics has gone from one percent of the market in 1974 to ten percent in 1977.**/

Cordis had an edge on competitors with its programmable unit but, according to industry sources, poor management and major recalls have caused the firm to lose market share overall. Industry observers, though, predict that Cordis' market share will stabilize over the next few years.***/

The future trends seem to indicate a growing pacemaker market with the larger firms taking most of the additional sales. Smaller firms are under increasing pressure from the dominant firms and many may drop out of the market in the 1980's.****/

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*/ The Lilly Study lists as one "physician perception" of Intermedics "Questionable Marketing Activities." See also, Littleford Interview; Staff Interview with Dr. Gross, Orlando, Fla. (August 1, 1978) (hereinafter referred to as "Gross Interview").

**/ Morgan Stanley Study at p. 6.

***/ Morgan Stanley Study at p. 4; Eberstadt Study at pp. 29-35; Gross Interview; Littleford Interview; Tew Interview.

****/ Medcor Interview; Morgan Stanley Study at p. 5.

D. Competitive Situation in the Pacemaker Industry

The domestic pacemaker market is extremely competitive. Every interview with an industry member supported this fact. Competition, though, does not occur at the price level, but rather, at the levels of reliability and service.

Price has never played a very important part in the pacemaker industry.*/ Most of the equivalent pacer brands sell at approximately the same price.**/ Price is naturally less important in an industry producing life sustaining products which are generally paid for by a party other than the patient.

Also, functional and technological differences between pacemaker brands have diminished to a great extent.***/ Sources indicate that product differentiation in the industry will continue to diminish as all of the major firms produce lithium powered pacers and programmable pacers and as there are no indications that there will be major technological improvements in pacemakers in the immediate future.****/

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*/ Intermedics Interview; Biotronics Interview; Medcor Interview; Medtronic Interview.

**/ Ventricular Demand Programmable Pacemakers generally sell for about $2400. Intermedics and Cordis pacers are priced a bit higher, for example, Intermedics' thin pacer, the Interlith, sells for $2600 and is not programmable.

***/ Morgan Stanley Study at pp. 6-7; Intermedics Interview; Cordis Interview.

****/ Morgan Stanley Study at pp. 6-7.

Brand loyalty is of uncertain significance. It is said that Medtronic still has a strong competitive edge in that many physicians were taught on and started with Medtronic's pacemakers.*/ But interviews with physicians and market share statistics would seem to indicate that doctors will readily switch pacemaker brands after major recalls or significant technological advances, such as lithium powered pacers.**/

Industry sources, physician surveys and staff interviews indicate that competition is occurring primarily in three areas: (1) product reliability; (2) company reputation; and (3) service and the quality of the sales force.***/ There appears to be little agreement, though, between physicians as to which pacemaker brand is more reliable or which company has the best reputation. And pacemakers in general are considered to be more reliable with the advent of the lithium powered programmable units.****/ Furthermore, recalls, which once may have proved nearly disasterous for a firm, will probably be of less significance in determining company reputation

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*/ Gross Interview.

**/ Burton Interview; Littleford Interview.

***/ Morgan Stanley Study at pp. 6-7; Lilly Study "Major Factors Considered When Selecting a Pacemaker;" Gross Interview; Littleford Interview; Burton Interview; Tew Interview.

****/ Burton Interview; Morgan Stanley Study at pp. 15-16.

now that each of the major firms has had at least one recall.*/ It is also predicted that recalls will occur less frequently with the hermetically-sealed lithium powered units.**/

As long as equivalent pacemaker brands are priced within the same range and have little functional or technological differences, it would appear that service and the quality of the sales force are the most important competitive factors in the pacemaker industry. This conclusion is supported by several facts. First, it is widely repeated in the industry that the competitive edge goes to the firm with the better, more aggressive sales force.***/ It is agreed that Intermedics went from a 0 percent share in 1973 to a 10 percent share in 1977 largely on the basis of its well qualified and aggressive sales force -- a sales force comprised principally of experienced salespersons from established firms.****/ Although Intermedics does have an innovative thin pacer, product reliability and company

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*/ Medcor Interview.

**/ Morgan Stanley Study at pp. 15-16; Eberstadt Study at p. 11.

***/ Morgan Stanley Study at p. 19; Eberstadt Study at 13.

****/ Eberstadt Study at pp. 37-38; Morgan Stanley Study at p. 5.

reputation are probably least well regarded of all the companies in the industry.*/

Second, there is, and has been for the past several years, a "mad dash" to provide more and better auxillary services. Pacemaker salespersons have always provided certain services such as: informing the physician about the product; being physically present during the implantation to perform tests and answer questions; and trouble-shooting after implantation.**/ Recently, the major pacemaker manufacturers, allegedly following the lead of Intermedics in many cases, have offered more and better auxillary services. Each of the major firms, for example, now offer free monitoring devices with each pacemaker implanted. In addition, each of the major firms are offering "lifetime warranties" on certain of their brands of pacemakers.***/

The free monitoring devices usually take the form of a transmitter given directly or indirectly to the patient and a receiver which may remain with the manufacturer or be "consigned" to the physician. The transmitter allows the patient, from his or her home, to take and transmit an EKG over the telephone to the manufacturer

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*/ During interviews, there were more questions as to the reliability of Intermedics products than other industry products. Tew Interview; Littleford Interview; Gross Interview.

**/ Cordis Interview; CPI Interview; Burton Interview.

***/ Allegedly, Intermedics started giving away follow-up equipment in 1976 and the other major manufacturers followed suit. It is unclear who first offered lifetime warranties. Medtronic Interview; CPI Interview.

or physician, thus saving the patient an office visit and charges for an EKG taken in the physician's office.*/ Lifetime warranties generally consist of a promise to replace a defective pacer and pay a certain amount of unreimbursed replacement costs.**/

III. Structural Analysis

The pacemaker industry is not a good candidate for a structural antitrust case. The industry is highly competitive -- competitive to the point where the major firms are giving away follow-up (monitoring) services in order to compete with one another. There have been two new entrants in the past five years -- CPI and Intermedics -- who have helped to end the near monopoly power held by Medtronic and who have added substantially to competition.

It is clear that Medtronic -- at one point the focus of the investigation -- does not have monopoly power and, although it is the dominant firm in the industry, is losing market share to newcomers CPI and Intermedics. No case of monopolization or attempt to monopolize could be brought against Medtronic at this time.

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*/ CPI Interview; Medtronic Interview; Staff Interview with Allen and Brooten, Washington, D.C. (June 23, 1978).

**/ CPI Interview, Medtronic Interview.

The competitive nature of the industry would also suggest that a "shared monopoly" or "oligopoly" structural analysis is not correct although it is difficult to translate these theories into an industry where price is not a major competitive factor but reliability and service are. Perhaps it is enough to say that competition has evoked massive research and development efforts on the part of the major industry members which has resulted in technologically better and more reliable pacemakers. In addition, it has resulted in additional and better services to pacemaker patients.

It is troubling that the top four firms hold over 80 percent of the pacemaker market. Although this memorandum recommends closing the present investigation, it also recommends that the pacemaker industry be watched carefully in pessimistic anticipation of the time when the top four firms "cooperate" more than they "compete." This is especially important in light of the recent announcement by Eli Lilly of its intentions to acquire CPI and industry rumors that other major firms now independent may soon be acquired.*/

Finally, there is the troubling question of price competition. As has been discussed before, there is little or no price competition in the industry. There is little the Commission can do, though, to stimulate price competition since its lack stems not so much from competitive conditions but rather from the fact that the industry

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*/ The Commission is presently investigating the proposed Lilly acquisition. It is vaguely rumored that Cordis may also be a candidate for acquisition.

produces a life sustaining medical device generally paid for by a third party. The Commission could, of course, petition H.E.W. -- the agency running the Medicare and Medicaide programs -- to review reimbursement rates for pacemakers and accessories but there is every indication that the industry itself will engage in more active price competition as product differentiation diminishes.*/ Again, the pacemaker industry should be monitored from this light.

In conclusion, then, staff recommends that the investigation into structural aspects of the pacemaker industry be closed while warning that changes in the industry may warrant another examination in the future.

IV. Analysis of Practices in the Pacemaker Industry

Since competition in this industry centers in part around sales persons and manufacturer services, practices in this area have been of central concern in this investigation. Early in the investigation, Commission staff received complaints about certain practices, most noteworthy of which were: (1) the giving away of monitoring devices and/or follow-up services;**/ and (2) commercial bribery of doctors by pacemaker manufacturers.***/ Staff itself

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*/ Morgan Stanley Study at pp. 6-7 and p. 16.

**/ Complaints here came from firms dealing exclusively in monitoring devices and follow-up services.

***/ The major complaint here was an anonymous letter. Staff later had conversations with an attorney whose clients allegedly had knowledge of such bribes.

decided to explore the giving of lifetime warranties after an article appeared on this topic in the Wall Street Journal.*/

A. Follow-up Services and Lifetime Warranties

Complaint letters suggested that the giving away of monitoring devices and/or follow-up services and lifetime warranties constituted illegal tie-ins.**/ While there may be technical tie-ins involved here, after investigation, staff feels that weighing the technical nature of the tie-in against the minor benefit to consumers and the major costs to the Commission an action here would have, closing the case would be the best possible resolution.***/

As described above, monitoring devices take the form of a transmitter -- which usually retails for $78-$143 -- which is offered to the patient and a receiver -- which might retail for $200 -- which is consigned or loaned to the physician or hospital. If the physician or hospital does not get the receiver, the pacemaker manufacturer performs the task of collecting -- or receiving -- the EKG

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*/ The article merely stated that Medtronic would be giving a lifetime warranty with certain models of pacemakers.

**/ As was mentioned above, complaint letters here came from two independant monitoring services. Staff was told by one that it lacked the resources to bring its own antitrust action against the major pacemaker manufacturers.

***/ Staff was advised in a "workload" meeting in June that this part of the investigation warranted little or no emphasis as the required impact on competition -- the "giveaways" were the result of intense competition -- was lacking.

and sending it to the physician. This service generally costs $25 when performed by an independent monitoring service firm.*/

These monitoring devices and services are generally offered to the patient "free of charge". While some manufacturers include the transmitter in the same box as the pacemaker, generally, the patient and/or physician can elect to send for a transmitter by means of a card included with the pacemaker.**/ Of the physicians staff interviewed, most preferred not to send for the transmitter; rather, they preferred to have the patient come into the office for a follow-up visit. Physicians generally admitted, though, that the patients could benefit by the devices and follow-up services -- these being more convenient and less expensive than office visits.***/

The facts show then that there is a product of some value -- monitoring devices and services -- being tied to another product -- pacemakers. This is not, though, the classic tie-in situation where a dominant firm coercively ties one product to the firm's major product.****/ And the benefit to consumers of Commission action here is not clear. The independent monitoring service which complained

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*/ Staff Interview with Brooten and Allen, Washington, D.C. (June 23, 1978).

**/ Intermedics Interview; CPI Interview; Medtronic Interview.

***/ Burton Interview; Gross Interview; Littleford Interview; Tew Interview.

****/ See, for example, Northern Pacific Railroad v. United States, 356 U.S. 1(1958); Siegel v. Chicken Delight, Inc., 448 F. 2d 43 (9th Cir. 1971), cert. denied 405 U.S. 955 (1972); Scherer, Industrial Market Structure and Economic Performance (1970) at pp. 505-06.

the most about the practice is flourishing rather than losing business -- no evidence has been presented that the consumer/patient is slowly losing choice in monitoring services. And when the patient and/or physician choose to accept the manufacturer's offer of monitoring devices and services, the patient benefits thereby.

Pursuing the tie-in theory would cost a great deal in Commission personpower and resources. There may come a time when transmitters and receivers are considered necessary by the physician and the manufacturer's offer of such devices is less of a choice. Here is where the mischief can be worked and here is where a commitment of Commission resources is necessary. For the present time, staff views these technical tie-ins as a result of intense competition which may or may not in the future result in the substantial impact required on competition to show public interest.*/

The same analysis is applicable to lifetime warranties on pacemakers. It appears that the giving of lifetime warranties is also a response to competitive conditions requiring ever greater service from pacemaker manufacturers.**/ In addition, this is not a situation where one product or serviced is tied coercively to another. Finally, lifetime warranties represent a benefit to consumers without extra charge.

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*/ One major manufacturer has discontinued offering follow-up services, in fact. CPI Interview.

**/ Intermedics Interview.

It must be noted here that there are features of some lifetime warranties that bear further scrutiny. For example, it is alleged that some manufacturers communicate warranties to physicians in their initial sales presentation but these warranties are never communicated to patients.*/ Also, as was discussed above, "lifetime" warranties pay only a certain amount of unreimbursed surgical and hospital costs -- not the total cost of replacement. The Dallas Regional Office is currently looking into pacemaker warranties and other health and safety features of pacemakers.**/

Staff recommends, therefore, that the Commission close its investigation into the giving away of monitoring devices and services and lifetime warranties. We also recommend that the files in this matter be studied and information possibly helpful to the Dallas investigation be xeroxed and forwarded to the Dallas Regional Office.

B. Commercial Bribery

It was also alleged by various industry sources that certain pacemaker manufacturers had given, or were giving, "bribes" to physicians to induce the physician to implant that firm's pacemakers. The most detailed allegations came from an attorney

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*/ Medtronic Interview.

**/ The persons working on this matter in Dallas, John McNalley and Robert Cheek, are just beginning their investigation. They, therefore, were unable to tell me much more about the investigation.

whose unnamed client had "knowledge" of such bribes and a sales representative for one of the major pacemaker manufacturers (who is probably the above mentioned attorney's client).*/ Each of the major manufacturers had also heard, through salespersons, rumors of bribes given to physicians.**/ Finally, some of the physicians interviewed had also heard rumors concerning bribes, again through competing salespersons.***/

The allegations, for the most part, concerned Intermedics salespersons. Specific allegations included: (1) the giving of payments per pacemaker implanted; (2) the giving of stock in the company; (3) the giving of land; (4) the giving of free trips and unlimited use of credit cards; and (5) the giving of fees for clinical and consulting work never actually performed.****/

To investigate these allegations, each of the major manufacturers and some smaller competitors, sales representatives, hospital administrators and physicians were interviewed.

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*/ If possible, staff would prefer to avoid citing names and titles in this memo because of the obvious harm disclosure would do to informants.

**/ Intermedics Interview; Cordis Interview; CPI Interview; Medtronic Interview.

***/ Gross Interview; Tew Interview.

****/ The same allegations were heard from both the attorney with the unnamed client and the sales representative.

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Hospital administrators were informative but claimed no knowledge of commercial bribery.*/ The major manufacturers had heard rumors from salespersons concerning bribery but none could substantiate the rumors or name offending salespersons or physicians.**/

Salespersons from the major manufacturing firms gave staff the most detailed accounts of bribery. One such person gave us names of doctors and administrators allegedly involved in bribery, and who allegedly had been offered bribes, and names of other physician groups which had suspiciously close links to certain pacemaker manufacturers.

In instances where investigation without process could be effective, interviews were held with named physicians. It was found that those physicians who supposedly had been offered bribes had not in fact -- or were unwilling to admit it.***/ In another case, a physician did admit to owning stock in Intermedics but any further details were unavailable without process.****/ It is rumored

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*/ Staff Interview with Nettles (Director of Purchasing, North Florida Regional Hospital), Gainesville, Fla. (July 11, 1978); Staff Interview with Nye and Pagnozzi (VA Hospital), Gainesville, Fla. (July 11, 1978).

**/ Cordis Interview; CPI Interview; Medtronic Interview.

***/ It had been suggested to staff that Drs. Gross, Tew and Littleford had been offered bribes. All admitted to hearing rumors about bribes but all said they lacked personal knowledge of such.

****/ Burton admitted to acquiring Intermedics stock after he had started using that company's pacemakers. The S.E.C. investigated Intermedics for violations of the laws it enforces. Although staff has not seen the files in this matter, we understand that the investigation probed superficially into commercial bribery and found that while payments had been made in the past to physicians from Intermedics reps, there was no evidence found that the practice was continuing.

that the last interview touched off a move by Intermedics to stop doctors who use their pacemakers from talking to FTC staff.*/

The investigation, then, is at an important juncture. To go forward would require process powers to reach medical firm records and perhaps personal records of salespersons and physicians. An attempt was made to go about the investigation from the other end -- physicians who had been offered bribes but had not accepted. This, though, proved futile. The next logical step would be to attempt to prove that "named" physicians did in fact accept some kind of bribe to implant certain brands of pacemakers. This, though, is a difficult task, requiring many more resources and an expertise in criminal-type investigations. Since staff was unable to evidence the kind of substantial competitive impact of bribes which would warrant additional resources and expenditures, staff recommends that the matter be forwarded to appropriate Department of Justice personnel who can investigate specific allegations of bribery and bring specific charges against the participants.**/

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*/ The rumor comes from the above-mentioned attorney with the unnamed client and was indirectly substantiated by a phone call I received from Intermedics' counsel.

**/ Perhaps the DOJ might investigate this as Medicare/ Medicaide fraud.

Staff recommends, therefore, that the Commission close its investigation of commercial bribery in the pacemaker industry and forward a memorandum to the appropriate Department of Justice personnel outlining steps already taken in the investigation of this matter and "leads" to further investigatory steps.

Respectfully submitted,

Patricia S. Bangert 12/8/78

Patricia S. Bangert
Attorney
Bureau of Competition

APPROVED:

Linda R. Blumkin
Assistant Director
Bureau of Competition

Alfred F. Dougherty, Jr.
Director
Bureau of Competition

APPENDIX R

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

HOUSTON DISTRICT
NORTH CENTRAL BUILDING
1440 NORTH LOOP, SUITE 250
HOUSTON, TEXAS 77009
713 226 5591

April 12, 1978

Mr. Willie A. Meadows
7235 Amarillo Ave.
Houston, TX. 77020

Dear Mr. Meadows:

This replies to your letter of March 17, 1978 concerning a pacemaker manufactured by Medtronic, Inc., Minneapolis, Minnesota.

We are requesting an investigator visit with you concerning specific pacemaker, its serial number and model; however, in the meantime, we suggest that you write directly to Medtronic, Inc., Minneapolis, Minnesota, and relay to them your difficulties concerning the warranty on the explanted pacemaker. Since the pacemaker's warranty and representations of it by Medtronic Sales, Inc. of Houston may be of interest to the Federal Trade Commission, we suggest you contact their local office and discuss your problem of warranty with them.

For your information, we are advised that Medtronic has paid as much as $400 toward the medical costs of explanting and implanting pacemakers. While we do not know if your surgery qualifies, you may wish to discuss this matter in your letter to Medtronic.

Sincerely,

Kenneth P. Ewing
Compliance Officer
Houston Section

sr

FEDERAL TRADE COMMISSION
Chicago Regional Office

Room 1437
55 East Monroe Street
Chicago, Illinois 60603
Area Code 312 353-4423

June 20, 1978

Mr. Willie Meadows
7235 Amarillo Avenue
Houston, Texas 77020

Re: FTC Ref. #150-7

Dear Mr. Meadows:

Thank you for your letter telling me of your dissatisfaction with Medtronic, Inc.

The information provided by you will be given consideration and if it should appear that the company is in violation of any of the laws administered by the Federal Trade Commission, appropriate action may be taken to prevent the continuance of such practices.

Corrective action taken by the Commission must be in the interest of the general public; accordingly, its remedies are not designed or applied to settle individual differences between a consumer and a warrantor.

We have, however, enclosed a pamphlet explaining your rights and responsibilities under the Magnuson-Moss Warranty Act. You should note that for products manufactured after July 4, 1975 the law allows you to bring an action against a warrantor for failure to comply with the provisions of a written warranty. The law also allows a consumer to bring an action when he is damaged by the failure of a warrantor or supplier to comply with state warranty laws.

In most cases, your state court would be the appropriate place in which to bring a Magnuson-Moss action. A consumer who is successful in such an action may obtain attorney's fees and costs. Should you desire to bring an action without an attorney, it would be helpful for you to check your state law to determine those courts where you may plead your own case.

Should you have any further questions, please do not hesitate to contact me.

Very truly yours,

FEDERAL TRADE COMMISSION

Benita A. Sakin

Benita A. Sakin
Attorney
Chicago Regional Office

BAS:jd
Encl.

Federal Trade Commission

Dallas Regional Office

Suite 2665
2001 Bryan Tower
Dallas, Texas 75201
(214) 749-3056

May 25, 1978

Willie A. Meadows
7235 Amarillo Avenue
Houston, Tex. 77020

Corres. No.: 81059
Re: Medtronic, Inc.

Dear Mr. Meadows:

This is to acknowledge your recent correspondence regarding the above named company. Your complaint has been referred to the Federal Trade Commission's Regional Office in Chicago, since the company involved in your complaint is headquartered in the region served by that office. Please direct all further communication this subject to that office.

Thank you for bringing this matter to the Commission's attention.

Yours very truly,

Andrew Armstrong
Andrew Armstrong
Consumer Protection Specialist

AA/jr

cc: Federal Trade Commission
Chicago Regional Office
55 East Monroe St., Suite 1437
Chicago, Illinois 60603

Federal Trade Commission

Dallas Regional Office

Suite 2665
2001 Bryan Tower
Dallas, Texas 75201
(214) 749-3056

May 25, 1978

Mr. Willie A. Meadows
7235 Amarillo Ave.
Houston, Texas 77020

Corres. No.: 81059
Re: Medtronic, Inc.

Dear Mr. Meadows:

This office is requesting further information concerning your complaint against the above firm. It is requested that you read the enclosed Privacy Act form and the Federal Trade Commission's complaint form and should you decide to respond to the undersigned's request please sign and return a copy of the Privacy Act form and the complaint form with your response.

You are advised that the undersigned will not forward such information to the Chicago regional office of the Commission.

Please state in detail how the pacemaker was secured by you. Was it ordered by your Doctor and billed to the hospital and subsequently billed to you or to an insurance company?

You state that the pacemaker had to be removed on December 30, 1977 with a diagnosis of pacemaker failure. Would you explain how you received information that there was such a failure and if possible precisely what the failure was.

You mentioned that the initial pacemaker was billed to your hospital and that the subsequent pacemaker was also billed to your hospital. Would you please explain whether you paid directly for each of these or whether the insurance company paid for these.

Would you please detail how and when the initial pacemaker was returned to the manufacturer and by whom. Would you also provide copies of any documents from the manufacturer

informing you or others that there would be no replacement credit on the initial pacemaker remo

Would you please explain how and when you received a copy of a document entitled "For the Patient Limited Warranty and Replacment Credit Agreement for Medtronic Implantable ~~Post~~ Pulse Generators".

Enclosed for your information and guidance is a document entitled "Warranties: There ought to be a law" published by the Federal Trade Commission.

Enclosed is a pre-paid postage envelope for return of your response.

Thank you for your cooperation.

Sincerely,

Andrew Armstrong

Andrew Armstrong
Consumer Protection Specialist

Medtronic, Inc.
3055 Old Highway Eight
P.O. Box 1453
Minneapolis, Minnesota 55440
Telephone 612/574-4000
Cable: Medtronic Telex: 29-0598

Medtronic

June 7, 1978

Mr. Willie A. Meadows
7235 Amarillo Avenue
Houston, TX 77020

Ref: Explanted 6P27075/Implanted MA0022249R

Dear Mr. Meadows:

I am writing with regard to your letter to the President of Medtronic, Inc. which he forwarded to me for a reply.

Enclosed for your review is a complete portfolio of literature, which includes a patient booklet and data sheet on Model 5972. I should mention that the booklet, "Pacing Your Heart," refers to all types of pacemakers. Consequently, the guidelines on pages 14-17 of this booklet may be somewhat conservative, as our tests have indicated that the Model 5972 pulse generator is not apt to be affected by most electrical appliances and devices.

Our records indicate that we received the removed unit, 6P27075. Since then it has been analyzed by our Returned Product Department and a report of the results was sent to Doctor David Sufian.

Under the terms of our Disclaimer and Replacement Credit Agreement, a removed unit must be replaced with a similar unit of our manufacture in the same patient prior to 30 months of use, in order to qualify for credit. In addition, the removed unit must have failed to function within tolerances for performance specifications established by Medtronic or must have complete exhaustion of one or more battery cells. We are unable to consider this unit for credit since the unit was found to be functioning normally. You may wish to discuss the reasons for removal with your physician.

Thank you for your letter. I am sincerely sorry I am unable to be of more assistance. However, please feel free to contact us again if you have any further questions. And if you are ever in the Minneapolis area, we would be pleased to have you visit our facilities. Please contact us a week or two in advance so that we can schedule a tour for you.

Sincerely,

MEDTRONIC, INC.

Linda McRoberts

Linda Plahn McRoberts
Patient Communications Supervisor

pcm

Enclosure

The Attorney General of Texas

JOHN L. HILL
Attorney General

Supreme Court Building
P.O. Box 12548
Austin, TX. 78711
512/475-2501

701 Commerce, Suite 200
Dallas, TX. 75202
214/742-8944

4824 Alberta Ave., Suite 160
El Paso, TX. 79905
915/533-3484

723 Main, Suite 610
Houston, TX. 77002
713/228-0701

806 Broadway, Suite 312
Lubbock, TX. 79401
806/747-5238

4313 N. Tenth, Suite F
McAllen, TX. 78501
512/682-4547

200 Main Plaza, Suite 400
San Antonio, TX. 78205
512/225-4191

An Equal Opportunity
Affirmative Action Employer

April 20, 1978

Willie A. Meadows
7235 Amarillo Ave.
Houston, Texas 77020

RE: Your Complaint Against
Medtronic, Inc.

Dear Mr. Meadows:

We have openend a complaint file to attempt to assist you in resolving your problem. The Consumer Protection Division of the Attorney General's Office administers a complaint mediation process wherein both parties to a consumer transaction are asked to state their position in the matter. Each complaint is evaluated by this office and we attempt to assist in resolving valid complaints which come under the Texas Deceptive Trade Practices-Consumer Protection Act. It is important for you to understand that while we will make every effort to resolve this matter to your satisfaction, the Attorney General's Office cannot go to court over every complaint. Moreover, we cannot act as either party's attorney or give legal advice.

If your claim is substantial, you may wish to consult a private attorney while we process your complaint. If your complaint comes under the Consumer Protection Act, you may seek three times your actual damages, court costs, and attorney's fees through a private attorney.

We would ask your patience because each complaint is different. Some are resolved within a few weeks, but others may take longer, depending on the nature of the problem. In any event, we will inform you of the outcome of your complaint. It is very important that you advise us immediately if your complaint is resolved so that our file will be current.

Thank you again for your interest in contacting us. We hope we will be able to assist you.

Very truly yours,

Nicolas J. Perez
Assistant Attorney General
Consumer Protection Division

By: Joyce Lord
Joyce Lord

NJP/du

FEDERAL TRADE COMMISSION.
BUREAU OF CONSUMER PROTECTION.
2001 BRYAN TOWER
DALLAS TEXAS, 75201

Mr. Dan L

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DEAR SIR'S
I WILLIE A. MEADOWS. 7235 AMARILLO AVE, HOUSTON TEXAS, 77020. PHONE 1-713-674-8104
I AM APPLYING TO YOU FOR ASSISTANCE, IN REGARDS TO A WARRANTY ON A PACEMAKER. ISSUED TO ME WITH A PACEMAKER. BY MEDTRONIC INC, 3055 ### OLD HIGHWAY EIGHT. P.O. BOX 1453. MINNEAPOLIS, M.N. 55440. ######. U.S.A. PHONE 1-612-574-4000. THIS PACEMAKER IN QUESTION, WAS ISSUED BY MEDTRONIC SALES INC. 4550 POST OAK PLACE, HOUSTON TEXAS. 77027 PHONE 1-713-521-0096. THIS PACEMAKER WAS IMPLANTED IN ME, WILLIE A. MEADOWS. DATE 2-14-1977 AT EASTWAY GENERAL HOSPITAL INC. 9339 NORTH EAST LOOP. HOUSTON TEXAS. 77029. PHONE 1-713-675-3241. SURGERY PERFORMED BY DAVID SUPIAN (D.O.P.A.) 1440 NORTH LOOP, SUITE 185. HOUSTON TEXAS PHONE 1-713-868-4281. AND WAS ASSISTED BY ALEXANDER P. REMENCHIK, (M.D. F.A.C.P. P.A.) 150 WEST PARKER Rd SUITE 701. HOUSTON TEXAS. 77076. PHONE 1-713-697-1384. THIS PACEMAKER IN QUESTION, HAD TO BE REMOVED. 12-30-1977. PACEMAKER FAILURE, DIAGNOSED. THIS PACEMAKER # CARRIED A 30 MONTH WARRANTY, AND WAS REMOVED AFTER 11 MONTHS OF SERVICE LEAVEING 19 MONTHS OF WARRANTY THAT MEDTRONIC INC. WONT MAKE GOOD. THIS PACEMAKER WAS BILLED TO MY HOSPITAL BILL EASTWAY GENERAL HOSPITAL INC. FOR THE SUM OF $2.046.00. AND $2.304.50 WAS BILLED HOSPITAL FOR NEW GENERATOR TO REPLACE THE ONE THAT WAS REMOVED. 12-30-1977. NO REBATE ALLOWANCE MADE ON NEW GENERATOR. I FEEL I AM DUE 19 MONTHS REBATE AT $68.20 PER MONTH, ######## A TOTAL OF $1.295.80. I AM SENDING WITH THIS LETTER A COPY OF THE WARRANTY THAT WAS ISSUED ON THE PACEMAKER IN QUESTION. THANKING YOU FOR ANY ASSISTANCE AVAILABLE.

(PACEMAKER IDENTIFICATION CARD)
MEDTRONIC INC. MINNEAPOLIS. M.N.
PULSE GENERATOR.
(MODEL 5950) (SERIAL NO. 6P27075)
(PULSE RATE 72) (LEAD NO. 6977-35

RESPECTFULLY YOURS
Willie A. Meadows
WILLIE A. MEADOWS
7235 AMARILLO AVE
HOUSTON TEXAS. 77020
PHONE 1-713-674-8104